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Quality Assurance Program
Annual Trending Report

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National Spent Nuclear Fuel Program Quality Assurance Program Annual Trending Report

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EXECUTIVE SUMMARY

This report documents the analysis of Quality Assurance (QA) deficiencies to identify areas for improvement for the National Spent Nuclear Fuel Program (NSNFP). Deficiencies are identified as Deficiency Reports (DRs) and Corrective Action Requests (CARs). DRs/CARs, which are tracked in the National Spent Nuclear Fuel Program (NSNFP) QA Corrective Action Tracking Trending System database, were categorized into the following three groups for analysis:

- NSNFP Project Support Organization (PSO) and QA Support
- DOE Spent Nuclear Fuel (SNF) Sites
- NSNFP suppliers.

Data for individual organizations were analyzed. This analysis identified the following organization-specific results:

NSNFP PSO and QA Support

The evaluation of data shows a steady decline in number of deficiencies from 33 in 1999, to 30 in 2000, to 20 in 2001, to 15 in 2002. There are no significant increasing trends. However, analysis of subject codes, direct and root cause codes for the NSNFP identified deficiencies in areas related to Quality Assurance Management accountability, acceptance of supplier QA programs prior to receipt of services, and personnel not conducting work to approved procedures and or using procedures improperly. The corrective actions for these conditions were closed or nearing final verification of closure at the time this trending report was prepared. Corrective actions are in progress to address deficiencies identified by the Office of Civilian Radioactive Waste Management (OCRWM) Office of Quality Assurance (OQA) audit EM-ARC-02-10 and by the Bechtel SAIC Company (BSC) supplier survey BQA-FS-03-04. No further action is required as a result of this evaluation.

Hanford SNF

During 2002, two audits were performed and documented in reports 02-RLSNF-AU-001 and –003. The evaluation of deficiency codes of the Hanford SNF program found continued satisfactory performance, as reflected by the results of audits and surveillances. No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timeliness of corrective action. No further action is required as a result of this evaluation.

INEEL SNF

During 2002, two evaluations of the INEEL SNF program were documented in the site qualification audit 02-INEEL-AU-001 and surveillance 02-SUPP-S-006. The INEEL has demonstrated improved performance under the current program. No CARs were identified during 1999 to 2002. No further action is required as a result of this evaluation.

ORNL SNF

The annual Oak Ridge National Laboratory (ORNL) site audit including data package assessment was conducted in September 2002. The evaluation of deficiency codes for the ORNL SNF QA program found continued satisfactory performance in 2002. There are no adverse trends identified at ORNL for this

report. The SNF canister work was completed in 2002 and closed the last remaining open DR. No further action is required as a result of this evaluation.

SRS SNF

The annual Savannah River Site (SRS) audit (02-SRS-AU-001) was conducted in March 2002. The results were satisfactory, showing that the demobilization of the SRS National Spent Fuel program was complete. The final report was issued on January 16, 2003.

The 2001 NSNFP trend analysis report from last year identified an increase in the frequency of SRS personnel not using procedures or using procedures improperly. As a result of the adverse trend, CAR number 01-SRS-02/22-01-CAR-001 was issued. The CAR was closed on April 3, 2002, based on remedial actions including revised work procedures and practices, and objective evidence of corrective action closure. There is no indication of a trend adverse to quality. No further action is required as a result of this evaluation.

NSNFP Suppliers

The NSNFP suppliers are Argonne National Laboratory-West and -East, Battelle Pacific Northwest National Laboratory, John Marvin, Inc. (JMI), and LMES-OR-Y12. With the exception of JMI, the NSNFP work provided by the suppliers was suspended, and the scheduled NSNFP surveillances were cancelled due to budget adjustments in 2002. The NSNFP QA Support staff only performed an evaluation of JMI. All DRs are closed. No new work is identified. No audits or surveillances are identified on the NSNFP assessment schedule. The trending results have not changed from the 2001 trending report.

JMI was the only supplier with any activity to be discussed in the 2002 trending analysis report. DR number 01-JMI-AU-004-DR-001 was closed on June 24, 2002. The DRs for all suppliers are closed.

No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timelines of corrective action for any of the NSNFP suppliers. No further action is required as a result of this evaluation.

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Quality Assurance Program Annual Trending Report

1. INTRODUCTION

1.1 Purpose and Scope

This report documents the analysis of Quality Assurance (QA) deficiencies for the identification of trends adverse to quality in the National Spent Nuclear Fuel Program (NSNFP). The analysis performed meets the requirements set forth in Section 16.2.6, "Quality Trending" of DOE/RW-0333P, *Quality Assurance Requirements and Description* (QARD). The trend analysis was performed in accordance with NSNFP Quality Assurance Staff (QAS) Procedure QAS 16.03. The data analyzed are categorized into three groups: NSNFP, Spent Nuclear Fuel (SNF) sites, and NSNFP suppliers.

1.2 Description of Trending Process and Methodology

Deficiencies are categorized as conditions adverse to quality and significant conditions adverse to quality, and are documented as a Deficiency Report (DR) or Corrective Action Request (CAR) respectively. DRs/CARs are assigned subject codes and direct cause codes. Significant conditions adverse to quality documented as CARs are additionally assigned a root cause code, based on formal root cause analysis. Codes are recorded in the NSNFP QA Corrective Action Tracking Trending System (CATTS) to facilitate analysis. The codes are sorted into three groups, the NSNFP, SNF sites, and NSNFP suppliers to facilitate analysis by calendar year. Other sources of information are also used for analysis to identify trends adverse to quality. Previous NSNFP QA Support trend analysis reports are used in analyses.

Subject codes are assigned to the DR/CAR that reflect the primary QARD requirement that is violated. Direct cause codes are the apparent cause of a condition adverse to quality. Root cause codes reflect the identified root cause that results from formal analysis. The first two codes, subject and direct cause, are subjective and are validated by review of the DRs/CARs during analysis. Root cause codes reflect the results of formal analysis and do not require validation.

Subject codes, direct cause codes, and root cause codes are used to compare the frequency of occurrence of like deficiencies. Codes are sorted by organization for each calendar year to identify an increase in the frequency of occurrence over time. Where an increase in frequency is identified, each individual DR/CAR is evaluated to validate that common issues are identified and determine if an adverse trend is present.

Subject codes, direct cause codes, and root cause codes are evaluated by Pareto analysis for each organization within a respective group. This analysis identifies the most frequent occurrence of deficiency codes. DRs/CARs are evaluated for the highest occurrence of a code to validate that common issues are identified. The highest occurrence of a code that reflects a common issue may represent an indicator of an adverse trend.

The DRs/CARs are evaluated for timeliness of corrective action, including (as applicable) a discussion of ineffective or overdue corrective actions for each organization. The duration of closed and open DRs/CARs are compared by calendar year to determine if an adverse trend in timeliness of corrective action is present.

Potential adverse trends are evaluated against the criteria for trends adverse to quality in procedure QAS 16.03 "Quality Assurance Trending." If the analysis finds the trend to be adverse to quality, then a review of open and recently completed correction actions is performed to determine whether mitigating actions are in process that may resolve the adverse trend. If there are no mitigating actions, then an evaluation of the trend for a significant condition adverse to quality is performed to determine whether a CAR will be issued to the responsible organization.

The discussion for each organization includes a description of documentation used as a part of the analysis, evaluations of selected subject and direct cause codes, and conclusions regarding trends adverse to quality. Attachment A provides tables that summarize the subject codes, direct cause codes, and root cause codes. Attachment B shows figures for the timeliness of DR closure through December 31, 2002. Attachment C lists the DRs, CARs, and CDAs that were analyzed for this trending report. Attachments D and E provide a list of subject codes and direct and root cause codes respectively. Administrative controls that may address adverse trends, lack of timely corrective action, or indicators for adverse trends are discussed. Conclusions that require action by management are identified under the Executive Summary and Results.

2. ANALYSIS

2.1 National Spent Nuclear Fuel Program

The NSNFP is composed of a QA Support organization and a Project Support Organization (PSO). DRs are assigned to each organization recognizing unique responsibilities, however, the analysis evaluated the data as representative of one organization.

2.1.1 Subject Codes

The evaluation of subject codes for the NSNFP indicates an overall improvement in QA program implementation from 1999 through 2002. An overview of the frequency of occurrence for subject codes indicates two categories of increased frequency for subject codes A.03 and G.06, both showing two counts in 2002. These two increasing indicators contrast to the other 10 general subject code categories, where overall frequencies remained the same or decreased from the previous three years evaluated.

Subject Code A.03, Quality Assurance Management
The frequency of occurrence of deficiencies under subject code A.03 has shown an increasing trend from one in 1999, zero in 2000, one in 2001, to two in 2002. The DRs address the following deficiencies:

- Deficiency Report 99-NSNF-QAMA-001 identified general deficiencies in the NSNFP QA Support function (roles and responsibilities) as they relate to, and interface with, other U.S. Department of Energy Idaho Operations Office (DOE-ID) QA functions. The subject code A.03 was assigned to this condition. The DOE-ID reorganization resolved the corrective actions.
- Deficiency Report 01-NSNFP-AU-001-CDA-001 addressed a conflict of interest in the NSNFP and DOE-ID organizational chart. The subject code A.03.2.1 was assigned to this condition. The problem was corrected during the assessment by reissuing Organization Charts to reflect the separation of responsibilities.
- Deficiency Report 02-NSNF-AU-001-DR-002 addressed a condition adverse to quality for the NSNFP QA Program Plan, which showed the QA Program Manager (QAPM) was not at the same or higher organizational level as the NSNFP Program Manager. The subject code A.03.2.6 was assigned to this condition. The QAPP was revised to clarify organizational independence of the QAPM through the Assistant Manager, DOE-ID to the Manager, DOE-ID.

- Deficiency Report 02-NSNF-AU-001-CAR-002, Revision 1 identified a significant condition adverse to quality regarding independence of cost and schedule. The subject code A.03.2.1 was assigned to this condition. Subsequent evaluation of the extent of condition found the NSNFP itself has little decision-making authority on final fiscal year (FY) budgets. The root cause analysis found that there is sufficient and appropriate independence of cost and schedule.

Evaluation of the DRs under subject code A.03 do not reflect a repeat of the same deficiency or an increasing frequency of the same deficiency. The corrective actions are viewed as adequate to address the emergent trend adverse to quality. The CDA (corrected during audit) is a singular event by definition and is not tied to a process deficiency. No corrective actions resulted from the root cause analysis of the CAR event. No further action is required by this report.

Subject Code G.06, Acceptance of Items or Services
The frequency of occurrence of subjects under the criteria of G.06 changed from zero in 1999, 2000, and 2001 to two counts in 2002. The DRs for 2002 address the following deficiencies:

- Deficiency Report 02-NSNF-S-001-CDA-001 identified a condition adverse to quality where, contrary to PMP 4.01 Rev. 2/ICN 1, Section 4.d(2), Acceptance of Products and Services, no objective evidence of acceptance of services was found. The subject code G.06.3.4 was assigned to this condition. The evidence was provided by the technical lead, and the deficient condition was closed during the assessment.
- Deficiency Report EM-ARC-02-10/ EM(0)-03-D-005 addressed a condition adverse to quality where, QAPM correspondence to conditionally qualify the Idaho National Engineering and Environmental Laboratory (INEEL) SNF Program to RW-0333P represents a level of acceptance that is not identified by the QARD. The subject code G.06.3.5 was assigned to this condition. The implementing procedure PMP 7.01 was revised to include the option of conditionally qualifying a U.S. Department of Energy (DOE) SNF site QA program.

Evaluation of the DRs under subject code G.06.3 do not reflect a repeat of the same deficiency or an increasing frequency of the same deficiency. The CDA is a singular event by definition and is not tied to a process deficiency. There is no indication of a trend adverse to quality. The corrective actions were evaluated and are viewed as adequate. No further action is required as a result of this evaluation.

Areas Showing Improvement
Results of the subject code evaluation identified areas showing improvement. Subject codes B.01, Quality Assurance Program Documents, and E.01, Implementing Documents Requirements, identified one and zero counts for 2002. This is a significant improvement compared to the increasing trend that was previously identified in the 2001 trend report.

2.1.2 Direct Cause Codes

The evaluation of direct cause codes for the NSNFP indicates an overall improvement in QA program implementation from 1999 through 2002. The results indicate three categories of increased frequency for the NSNFP, direct cause codes 01C, 02Ab, and 03A. These three indicators contrast to 22 direct cause codes where overall frequencies remained the same or decreased from the previous three years evaluated. Direct Cause Code 01C had the highest counts for 2002 (3) and is evaluated below.

Direct Cause Code 01C, Error in Following the Procedure due to Confusing Format, Reference Data, etc.
There were three DRs in 2002 with the assigned direct cause code 01C, compared to zero for the previous 3 years. A review of the individual DRs with code "01C" reflect a common direct cause of error in following the procedure. There is no common deficiency because of the diverse nature of the subjects as described below, involving a procedure revision, timely corrective actions, and supplier evaluations.

- The CDA (02-NSNF-AU-001-CDA-002) addressed frequency of equipment calibration. The requirement was annual, whereas the test plan identified semiannual. The test plan was revised to agree with the annual frequency. The CDA is a singular event by definition and is not tied to a process deficiency.
- The DR (02-NSNF-AU-001-DR-001) addressed remedial actions, corrective actions, extent of condition evaluations, and root cause determinations that were not being completed as soon as practical. The closure of this DR showed that the long-term findings were closed and that NSNFP management has committed to timely closure of open corrective action and periodic evaluations to ensure commitments are met.
- The CAR (02-NSNF-AU-001-CAR-001) addressed a condition where a supplier evaluation was not performed prior to the start of work. The CAR was closed on January 31, 2003, while this trending report was prepared.

Pareto analysis of direct cause codes indicates a possible adverse trend for code 01C. However, corrective actions to preclude recurrence of this condition have already been identified in the closure of CAR 02-NSNF-AU-001-CAR-001. As part of the corrective actions for this CAR, the supplier and DOE site assessments (02-SUPP-S-006 and 02-INEEL-AU-001) were completed and showed no conditions adverse to quality related to performance of work. The issuance and implementation of the revised NSNFP manual in January 2002 has shown improvements in the reduction of personnel errors. All these corrective actions are found to be adequate mitigating factors to resolve the adverse trend. In addition, corrective actions are in progress to address deficiencies identified by the DOE Office of Quality Assurance (OQA) audit EM-ARC-02-10 and by the BSC survey BQA-FS-03-04 . No further action is required as a result of this evaluation.

Areas of Improvement
Results of the direct cause code evaluation identified areas of improvement. Improvement under the direct cause code of 02Ad "Procedure not used, or used improperly" is reflected with a decline from 13 (1999), 10 (2000), 9(2001), to 2 in 2002. Improvement was also shown in direct cause code 1 B g(4) "Procedure does not describe how the requirement will be implemented," which had zero DRs in 2002, after a 3-year increase of 1 in 1999, 2 in 2000, and 3 in 2001.

2.1.3 Root Cause Codes

The evaluation of root cause codes for the NSNFP indicates an overall improvement in QA program implementation. There were two significant conditions adverse to quality identified during 2002 and are discussed below. No adverse trends are identified from this analysis.

- Report 02-NSNF-AU-01-CAR-001 addressed a supplier evaluation was not performed prior to start of work. The CAR was closed on January 31, 2003, while this trending report was prepared. The root cause was attributed to 3Af, "Management System Inadequate Accountability." The root cause analysis determined that NSNFP management did not adequately enforce compliance to existing procedures related to qualifying INEEL supplier services prior to work being performed. This condition had been previously recognized by NSNFP management. Management had determined that the written program, (NSNFP procedures) which was in effect at the time the events took place,

should undergo a wholesale revision to provide a clearly defined work flow process. These changes were placed into effect January 15, 2002, and have invoked adequate processes to preclude the recurrence of this adverse condition. Effectiveness in implementing the revised procedures was evident by the reduction in personnel errors during 2002.

- Report 02-NSNF-AU-01-CAR-002, Revision 1 addressed a condition where the QA Support organization did not perform the assigned oversight duties because of the perceived lack of independence of cost and schedule. The CAR was closed on January 9, 2003, while this trending report was prepared. Results of the independent root cause analysis determined that there was no evidence of undue forces at work and that there was adequate independence of cost and schedule; consequently, no corrective actions were needed. The root cause was assigned as 3Ad, "Management System Standards, Policies, and Administrative Controls Changed Recently," to take into consideration the external factors influencing the FY 2002 budget. The effectiveness of root cause analysis and corrective actions identified by 02-NSNF-AU-01-CAR-002, Revision 1 will be evaluated during the NSNFP audits and surveillances scheduled for 2003.

There is no indication of a trend adverse to quality. No further action is required as a result of this evaluation.

2.2 Spent Nuclear Fuel Sites

Spent Nuclear Fuel sites are composed of Hanford, INEEL, Oak Ridge National Laboratory (ORNL), and the Savannah River Site (SRS). The analysis is performed for the individual sites. The basis of analysis is limited to the results of audits and surveillances performed by NSNFP QA.

2.2.1 Hanford

The evaluation of DRs for the Hanford SNF program showed changes from 22 CARs/DRs in 1999, 1 in 2000, 4 in 2001, to 21 in 2002. Examination of the data showed that Hanford has been responsive to addressing the problems as soon as possible. During 2000 to 2002, Hanford has closed 15 conditions during the assessments: 1 CDA in 1999, 4 CDAs in 2001, and 10 CDAs of 21 deficient conditions identified in 2002. During the same 3-year span, Hanford has not incurred any CARs, compared to having 4 CARs in 1999. Effectiveness of corrective actions will be evaluated during the NSNFP QA Support audits and surveillances of the Hanford SNF program that are scheduled for 2003.

The annual audit of the Fluor Hanford SNF Project QA program was documented in report 02-RLSNF-AU-003. The quality implementation audit of the Shippingport PWR Fuel Removal Project and Fluor Hanford River Corrridor Building 324 Fuel Transfer Project was documented in report 02-RLSNF-AU-001. Evaluation of the data showed there are 11 open DRs as of January 2, 2003. While this trending report was being prepared, 7 of 11 Hanford DRs were closed in February 2003. There is no indication of a trend adverse to quality. No further action is required as a result of this evaluation.

Evaluation of Subject Codes
A comparison of subject codes for 1999 through 2002 found an increase in subject code E01, "Implementing Document Requirements," changing from zero counts in 1999, 2000, 2001 to three DRs in 2002. Evaluation found no adverse trend, however, because two of the three reports were singular deficiencies that were readily corrected during the assessment (CDA).

Evaluation of Direct and Root Cause Codes
There were five DRs with a direct cause code of 02Ad, "Procedure Not Used, or Used Improperly." Evaluation of the data found no adverse trend code, because three of five were determined to be singular

deficiencies that were corrected during the assessment. Pareto analysis of subject codes, direct cause codes, and root cause codes for 2002 does not provide an indicator of adverse trends.

2.2.2 INEEL

The evaluation of DRs for the INEEL SNF program showed changes from 25 CAR/DRs in 1998, 1 in 1999, 0 in 2000, 1 in 2001, to 17 in 2002. The frequency of DRs correlates with the two site qualification audits performed in 1998 and 2002.

During 2002, two evaluations of the INEEL SNF program were documented in the site qualification audit 02-INEEL-AU-001 and surveillance of supplier activities 02-SUPP-S-006. The results identified 17 conditions (11 DRs and 6 CDAs). The INEEL has demonstrated improved performance under the current program. No CARs were identified during 1999 to 2002.

While this trending report was being prepared, 7 of 11 INEEL DRs were closed in February 2003. There is no indication of a trend adverse to quality. No further action is required as a result of this evaluation.

Evaluation of Subject Codes
The only subject code with more than one count was Subject code P.03.2. Management shall determine the extent of the adverse condition.

- DR 02-INEEL-AU-DR-008 involved timeliness of corrective action plan acceptance within the allotted 30-day period after discovery. This DR was closed via QA Support verification of evidence showing action tracking and management oversight.
- DR 02-INEEL-AU-001-DR-007 identified several DRs that lacked the extent of impact evaluations. Evaluation of the data indicated that INEEL personnel will review 80 reports from FY-01 and FY-02 to determine if the existing impact evaluations are adequate. Management has committed to performing investigative actions and to revise the implementing procedures. There is no indication of a trend adverse to quality. No further action is required as a result of this evaluation.

Evaluation of Direct and Root Cause Codes
Evaluation of the 17 INEEL DRs from 2002 showed 4 counts for direct cause code 03Ac, “Inadequate Communication of Standards, Policies, Administrative Controls (SPAC).”

- DR 02-INEEL-AU-001-DR-007 (see description above).
- DR 02-INEEL-AU-001-DR-002 found instances where the quality program (PLN-533) implementation matrix did not directly address the QARD requirements. PLN-533 and supporting documents were revised, and the DR was closed on February 4, 2003.
- CDA number 02-INEEL-AU-001-CDA-005 addressed material control and designation of QA hold areas. The condition was considered a singular incident and was corrected during the assessment.
- DR 02-INEEL-AU-001-DR-005, Revision 1 addressed lack of objective evidence to support the annual review of inspection and NDE personnel. The annual reviews were completed and the DR was closed on February 4, 2003.

Evaluation of the INEEL SNF data did not indicate common problem areas. There were no adverse trends for the subject and direct cause codes.

2.2.3 ORNL

The evaluation of DRs for the ORNL SNF program showed a low frequency of DRs with 1 in 1998, 2 in 2000, and 1 in 2002. The annual ORNL site audit including SNF canister data packages was conducted in

September 2002. The audit team found one DR (02-ORNL-AU-001-DR-001) regarding unapproved drawings in several data packages used for the SNF canister fabrication process. The ORNL completed a comprehensive check of all 62 data packages and determined that the deficiency only affected the initial group of canisters to be fabricated. The SNF canister work was completed in 2002 and closed the last remaining open DR.

The Second Quarter FY-03 NSNFP Assessment Schedule identifies a surveillance (03-ORNL-S-001) of SNF shipment activities pending completion of SNF shipments to the INEEL. No further action is required as a result of this evaluation.

2.2.4 SRS

The evaluation of DRs for the SRS SNF program showed overall declining trend from 2 CAR/DRs in 1998, 12 in 1999, 13 in 2000, 1 in 2001, to 0 in 2002. The annual SRS site audit (02-SRS-AU-001) was conducted in March 2002. No conditions adverse to quality were identified. The team found one concern whereby a demobilization plan for the Westinghouse Savannah River Company (WSRC) SNF program has not been formalized to identify and classify the documents and records. The NSNFP QA Support staff conducted a surveillance (03-SRS-S-001) of the WSRC Demobilization Plan in December 2002 to evaluate the performance and completeness of activities. The results were satisfactory, showing that the demobilization of the SRS SNF program was complete. The final report was issued on January 16, 2003.

The 2001 NSNFP trend analysis report from last year identified an increase in the frequency of SRS personnel not using procedures or using procedures improperly. As a result of that adverse trend, CAR number 01-SRS-02/22-01-CAR-001 was issued. Evaluation of the 2002 data showed that this CAR was closed on April 3, 2002, based on remedial actions including revised work procedures and practices, and objective evidence of corrective action closure. There is no indication of a trend adverse to quality. No further action is required as a result of this evaluation.

2.3 National Spent Nuclear Fuel Program Suppliers

The SNF suppliers currently approved to provide items and services to the NSNFP are Argonne National Laboratory-East (ANL-E), Argonne National Laboratory-West (ANL-W), Battelle Pacific Northwest National Laboratory (Battelle PNNL), John Marvin, Inc. (JMI), and Lockheed Martin Energy Systems-Oak Ridge-Y12 (LMES-OR-Y12). Audits for the suppliers are performed triennially. Surveillances are also performed to monitor supplier performance.

Because of budget adjustments in 2002, the NSNFP work provided by the suppliers was suspended, and the scheduled NSNFP surveillances were cancelled with exception of JMI. JMI was the only supplier with any activity to be discussed in the 2002 trending analysis report. The NSNFP had issued one deficiency to JMI, DR number 01-JMI-AU-004-DR-001, which was closed on June 24, 2002. The DRs for all suppliers are closed.

2.3.1 Argonne National Laboratory-East

The 2002 NSNFP budget considerations suspended work provided by suppliers. The NSNFP QA Support staff did not perform any evaluations. There were 4 DRs in 1999; all are closed. No new work is identified. No audits or surveillances are identified on the NSNFP assessment schedule. The trending results have not changed from the 2001 trending report.

2.3.2 Argonne National Laboratory-West

The 2002 NSNFP budget considerations suspended work provided by suppliers. The NSNFP QA Support staff did not perform any evaluations. There were 6 DRs in 1999 and 1 in 2000; all DRs are closed. No new work is identified. No audits or surveillances are identified on the NSNFP assessment schedule. The trending results have not changed from the 2001 trending report.

2.3.3 Battelle-Pacific Northwest National Laboratory

The 2002 NSNFP budget considerations suspended work provided by suppliers. The NSNFP QA Support staff did not perform any evaluations. There were 4 DRs in 1999; all DRs are closed. No new work is identified. No audits or surveillances are identified on the NSNFP assessment schedule. The trending results have not changed from the 2001 trending report.

2.3.4 John Marvin Inc.

JMI was the only supplier evaluated by the NSNFP QA Support staff during 2002. DR number 01-JMI-AU-004-DR-001 was closed on June 24, 2002. From 1999 through 2001, JMI has experienced three DRs and one CDA. Evaluation of the data did not identify an adverse trend regarding the subject codes or direct cause codes. All DRs are closed. No new work is identified. No audits or surveillances are identified on the NSNFP assessment schedule.

2.3.5 Lockheed Martin Energy Systems-Oak Ridge-Y12

The 2002 NSNFP budget considerations suspended work provided by suppliers. The NSNFP QA Support staff did not perform any evaluations. There were seven DRs in 1998; all DRs are closed. No new work is identified. No audits or surveillances are identified on the NSNFP assessment schedule. The trending results have not changed from the 2001 trending report.

3. CORRECTIVE ACTION TIMELINESS

The DRs/CARs were evaluated for timeliness of corrective action. Data for individual organizations, SNF sites, and suppliers were evaluated by calendar year to determine if an adverse trend in timeliness of corrective action is present. The CDAs were not included in the computed average, because the CDAs are singular incidents that are closed during the assessment, resulting in zero days for closure. The open CAR/DRs were included in the computed average using the number of days open as of January 2, 2003.

Overall performance of all the SNF programs has improved in providing timely corrective action. The NSNFP QA Support organization tracks and reports on a biweekly basis a summary report of all open DRs. During calendar year 2002, the number and average duration that DRs are open has dropped.

Attachment B presents figures for showing the timeliness of DR closure as of December 31, 2002. The Open reports are also included (black).

3.1 National Spent Nuclear Fuel Program

The NSNFP is composed by of the PSO and QA Support organizations. The two groups work to the same program management procedures. However, data were sorted to evaluate the individual organization duration. The figures in Attachment B show both the NSNFP PSO and QA Support organizations have improved their timeliness in reducing the average number of days to close DRs.

The average closure time for PSO reports declined from 358 days in 1999, to 347 in 2000, to 256 in 2001 to 229 in 2002. The NSNFP PSO organization has one open DR and one open CAR from 2002. At the time this trending report was being prepared, the CAR number 02-NSNF-AU-001-CAR-001 was closed.

The average closure time for QA Support reports showed an overall decline from 261 days in 1999, rising slightly to 294 days in 2000, dropping back to 174 days in 2001, and continuing a downward trend to an average of 123 days in 2002. The NSNFP QA Support organization has three open DRs from 2002. At the time this trending report was being prepared, DR numbers EM-ARC-02-10/EM(0)-03-D-005 and -007 were closed. The evaluation of data shows a declining in trend in the duration that a DR remains open. There is no further action required as a result of this evaluation.

3.2 Spent Nuclear Fuel Sites

The SNF sites are Hanford, INEEL, ORNL, and SRS. Data were sorted to evaluate the timeliness of DR closure by individual organization. The figures in Attachment B show declining trends, indicating improvement.

3.2.1 Hanford

The average closure time showed significant improvement from 407 days in 1999 to 126 days in 2002. Evaluation of the data for 2002 showed 10 CDAs and 11 DRs were identified within the Hanford SNF program. The 11 DRs were open as of December 31, 2002; however, 7 of 11 were closed in February 2003 when this trending report was prepared. The corrective actions for the 4 remaining open DRs entail procedure revisions, personnel training and oversight. There is no indication of a trend adverse to quality. No further action for Hanford is required as a result of this evaluation.

3.2.2 INEEL

The average closure time showed significant improvement. The first QA program qualification audit was performed in 1998. The results identified 25 findings (14 CARs and 11 DRs) that took an average of 766 days to close. The 2002 qualification audit of the INEEL nonlicensed SNF QA program identified 17 findings (11 DRs and 6 CDAs) and shows the average time the deficiency remains open has been reduced to 106 days. The 11 DRs were open as of December 31, 2002; however, 7 of 11 DRs were closed in February 2003 when this trending report was prepared. Corrective actions for the remaining DRs were in progress. There is no indication of a trend adverse to quality. No further action for the INEEL is required as a result of this evaluation.

3.2.3 ORNL

The evaluation of DR duration for the ORNL SNF program found satisfactory performance for 1998, 2000, and 2002. The single DR issued in 1998 was open for 281 days, two CDAs were identified during the 2000 audit, and one DR from the 2002 assessment was closed in 15 days. No audit or surveillance was conducted during 1999 or 2001. Individual duration history reflects satisfactory performance. The

extended duration for the DR issued in 1998 was in part due to coordinating the NSNFP QA Support schedule for verification of corrective action. There is no indication of a trend adverse to quality. No further action for ORNL is required as a result of this evaluation.

3.2.4 SRS

During 2002, no new DRs were identified, and the three remaining open reports (1 CAR and 2 DRs) were closed. CAR 01-SRS-02/22-01-CAR-001, issued as a result of the 2001 NSNFP trend analysis, was closed on April 3, 2002. The remedial actions and the objective evidence of corrective action closure was verified by NSNFP QA Support.

The annual SRS site audit (02-SRS-AU-001) was conducted in March 2002. Surveillance (03-SRS-S-001) of the WSRC Demobilization Plan Implementation and Completion was conducted in December 2002. No conditions adverse to quality were identified by these assessments. No further action for SRS is required as a result of this evaluation.

3.3 National Spent Nuclear Fuel Program Suppliers

The NSNFP suppliers are ANL-E, ANL-W, Battelle PNNL, JMI, and LMES-OR-Y12. These SNF suppliers are not audited on an annual basis, which does not provide sufficient data to establish trends. However, average duration of deficiencies (all closed) issued to the SNF suppliers reflect satisfactory performance

As required by RW-0333P, the NSNFP QA Support staff verifies that all DRs are resolved prior to acceptance of items and services. The duration for DR closure presented below is based on the final closure date. There is no adjustment to consider the interim period when verification of corrective action completion must be coordinated with the NSNFP QA Support assessment schedule. No further action for the NSFNP suppliers is required as a result of this evaluation.

Organization	CAR/DR Status	Number of Deficiencies (1998–2002)	Average Days open
ANL-E	Closed	4	210
ANL-W	Closed	7	190
Battelle PNNL	Closed	4	116
JMI	Closed	4	237
LMES-OR-Y12	Closed	7	85

4. RESULTS

Data for the NSNFP, individual SNF sites, and NSNFP suppliers were analyzed to identify organization-specific adverse trends. Subject codes, direct cause codes, root cause codes, and timeliness of corrective action completion were evaluated. The analysis of increases in frequency of codes, highest frequency of codes, and corrective action duration resulted in the identification of potential adverse trends in the NSNFP PSO and QA Support organizations. The analysis identified the following results.

NSNFP

The evaluation of data shows a steady decline in number of deficiencies from 33 in 1999, to 30 in 2000, to 20 in 2001, to 15 in 2002. There are no significant increasing trends. However, analysis of subject codes, direct and root cause codes for the NSNFP identified deficiencies in areas related to QA Management accountability, acceptance of supplier QA programs prior to receipt of services, and personnel not conducting work to approved procedures and or using procedures improperly. The corrective actions for these conditions were closed or nearing final verification of closure at the time this trending report was prepared. Corrective actions are in progress to address deficiencies identified by the OQA audit EM-ARC-02-10 and by the Bechtel SAIC Company survey BQA-FS-03-04 . No further action is required as a result of this evaluation.

Hanford SNF

During 2002, two audits were performed and documented in reports 02-RLSNF-AU-001 and –003. The evaluation of deficiency codes of the Hanford SNF program found continued satisfactory performance, as reflected by the results of audits and surveillances. No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timeliness of corrective action. No further action is required as a result of this evaluation.

INEEL SNF

During 2002, two evaluations of the INEEL SNF program were documented in the site qualification audit 02-INEEL-AU-001 and surveillance 02-SUPP-S-006. The INEEL has demonstrated improved performance under the current program. No CARs were identified during 1999 to 2002. No further action is required as a result of this evaluation.

ORNL SNF

The annual ORNL site audit including data package assessment was conducted in September 2002. The evaluation of deficiency codes for the ORNL SNF QA program found continued satisfactory performance in 2002. There are no adverse trends identified at ORNL for this report. The SNF canister work was completed in 2002, and ORNL closed the last remaining open DR. No further action is required as a result of this evaluation.

SRS SNF

The annual SRS site audit (02-SRS-AU-001) was conducted in March 2002. The results were satisfactory, showing that the demobilization of the SRS SNF program was complete. The final report was issued on January 16, 2003.

The 2001 NSNFP trend analysis report from last year identified an increase in the frequency of SRS personnel not using procedures or using procedures improperly. As a result of the adverse trend, CAR number 01-SRS-02/22-01-CAR-001 was issued. The CAR was closed on April 3, 2002, based on remedial actions including revised work procedures and practices, and objective evidence of corrective action closure. There is no indication of a trend adverse to quality. No further action is required as a result of this evaluation.

National Spent Nuclear Fuel Program Suppliers

The NSNFP suppliers are ANL-E, ANL-W, Battelle PNNL, JMI Inc., and LMES-OR-Y12. With the exception of JMI, the NSNFP work provided by the suppliers was suspended, and the scheduled NSNFP surveillances were cancelled due to NSNFP budget reductions in 2002. The NSNFP QA Support staff did not perform any supplier audits. All DRs are closed. No new work is identified. No audits or surveillances are identified on the NSNFP assessment schedule. The trending results have not changed from the 2001 trending report.

JMI was the only supplier with any activity to be discussed in the 2002 trending analysis report. The 2001 JMI DR 01-JMI-AU-004-DR-001 was closed on June 24, 2002. The DRs for all suppliers are closed.

5. SUPPORTING DOCUMENTS

1. National Spent Nuclear Fuel Quality Program Annual Trending Report, January–December 2000.

2. National Spent Nuclear Fuel Quality Program Annual Trending Report, January–December 2001.

Attachment A

Deficiency Reports Sorted by Subject and Cause Codes

Attachment A
Deficiency Reports Sorted by Subject and Cause Codes

NSNFP (PSO and QAS) Subject Code

NSNF_all Subj. Code	CY99	CY00	CY01	CY02
A.01		1	1	
A.02		1		
A.03	1			
A.03.2.1				1
A.03.2.6			1	
A.3.2.1				1
B.01.1				1
B.01.2		1	1	
B.01.2.1			2	
B.01.2.3	1			
B.01.2.4		1		
B.01.3.1.1	1			
B.01.3.3			1	
B.03	2	1		
B.1.2.2			1	
B.10.6.3	1			
B.12	2			
B.12.1		1		
B.12.1.2		2	1	1
B.12.1.4		1		
B.6				1
C.01.4	1	1		
C.02.1	1			
C.04.5.1.3	1			
D.01		1		
D.01.2.3	2			
D.01.3.1.1	1			
D.01.3.3.1	1			
D.01.3.3.2		1		
D.01.6		1		
E.01	6	2	4	
E.03	1			
E.03.1		1		
E.03.2	1			
E.05	1			1
F.05.3		1		1
F.05.4			1	
F.07.1.1		1		
F.07.2.2	1			
F.5.1			1	
G.02.1	1			1
G.03.4			1	
G.06.3.4				1
G6.3.5				1
J.09.1		1		
K.05.3				1
P.03.2		1		
P.04.2			1	
P.04.5.2				1
P.06.2		1		
P.06.3	1			
P.3.2				1
Q.02	1			
Q.02.2	1	2	1	
Q.03.7		1		
Q.05.1.1			1	
Q.08.1.1			1	
R.01.1			1	
R.01.6		1		
R.02.6		1		
R.08.5	1			
S.01.1		2		
S.02	1			
S.06.1.1	1			
S.06.2.2		1		
S.07		1		
U.06.3.2				1
V.01	1			
V.01.3				1
total	33	30	20	15

NSNFP (PSO and QAS) Direct Cause Code

NSNF_all Direct Cause Code	CY99	CY00	CY01	CY02
01 A a	1	1		1
01 B	2	6		1
01 B d (1)			2	
01 B d (2)	4			
01 B f	1			
01 B g (1)	1			
01 B g (2)	2	5		
01 B g (3)	2			
01 B g (4)	1	2	3	
01 C				3
01 C f	1		1	1
02 A		2		
02 A a				1
02 A b				2
02 A c				1
02 A d	13	9	10	2
03 A				2
03 A c	1			
03 A d		2		1
03 A f		1		
03 B a			1	
03 F a	1			
05 A b	1			
05 B a		1		
08 A b	1			
08 A c		1		
08 D	1			
10 A			2	
10 C			1	
total	33	30	20	15

NSNFP (PSO and QAS) Root Cause Code

NSNF_all Root Cause Code	CY99	CY00	CY01	CY02
01 B h	1			
02 A	1			
03 A	1			
03 A a	2			
03 A c	2			
03 A d				1
03 A f				1
03 D	2			
total	9			2

Hanford
Subject Codes

HANFORD SUBJECT	CY99	CY00	CY01	CY02
A.02	1			
A.06.1				1
B.01				2
B.01.2.1	1			
B.01.3	1			1
B.02.7	1			
B.09	1			
B.10.6.3				1
B.10.7	1			
B.12.2.1				1
C.01				1
C.01.3	1			
C.09.1	1			
E.01				3
F.03				1
F.05.2				1
J.06.2			2	
J.07.1	1			
L.01.1	1			
O. 01.2	1			1
O.04.4				1
P.03.3		1		
P.04.2			2	
P.05	1			
P.6.2				1
Q.02.1				1
Q.03.6.3				1
Q.05.1				1
Q.05.1.1				1
Q.06.1				1
R.21.2.1				1
S.01.2.1	1			
T.01.3	1			
T.02	1			
U.01.1	1			
U.01.2	1			
U.02.1	1			
U.03	1			
U.06.1.1	1			
V.01	2			
total	22	1	4	21

Hanford
Direct Cause Codes

HANFORD DIRECT	CY99	CY00	CY01	CY02
01 A a	2			1
01 B d (2)	4			4
01 B g (2)	2			1
01 B g (3)	1			
01 B g (4)				1
01 C d				1
02 A a			2	1
02 A b				4
02 A d	7	1	2	5
03 A c				2
04 Bc				1
05 A c (1)	1			
05 A c (2)	1			
05 B b	1			
08 A b	1			
08 C	1			
08 D	1			
total	22	1	4	21

Hanford
Root Cause Codes

HANFORD ROOT	CY99	CY00	CY01	CY02
01 B g (1)	1			
03 A a	1			
03 A c	1			

INEEL
Subject Codes

INEEL subject	CY98	CY99	CY00	CY01	CY02
A.02	1				
B.01	1				
B.01.2	3				
B.01.2.1					1
B.01.2.2	1				
B.01.3	1				
B.01.3.1.1					1
B.02	1				
B.05	2				
B.06	1				
B.07	1				
B.11	1				
B.11.2					1
B.12	1				
B.12.1.4				1	
C	1				
C.05.1					1
E.01	1				1
E.1					1
F	1				
G.06.3.4	1				
K.01.4					1
L.01.6	1				
L.03.2.1					1
L.03.2.2.1					1
M.01	1				
M.01.1					1
N.01.1					1
O.01	1				
O.03.1					1
P	1				
P.03.2					2
Q	1				
Q.02.1.1					1
Q.03.4					1
Q.05.1					1
R.03	1				
R.06.3		1			
V.01	1				
total	25	1		1	17

INEEL
Direct Cause Codes

INEEL direct	CY98	CY99	CY00	CY01	CY02
01 A a	2				
01 B a					1
01 B d (2)	4				1
01 B e	1				
01 B g (1)	1				
01 B g (2)	10				1
01 B g (3)	3				
01 D					1
02 A			0	1	
02 A a					2
02 A b					3
02 A d	2	1			1
03 A c					4
03 A f					2
04 C a	1				
08 A b	1				
10 C					1
total	25	1	0	1	17

INEEL
Root Cause Codes

INEEL root	CY98	CY99	CY00	CY01	CY02
01 A a	1				
01 B c	1				
03 A b	1				
03 A c	6				
03 A d	1				
03 A f	2				
03 C	1				
08 C	1				
total	14				

Oak Ridge
Subject Code

ORNL Subject	CY98	CY99	CY00	CY01	CY02
F.06.2					1
Q.01.1.7			1		
R.01.5	1				
R.21.2.1			1		

Oak Ridge
Direct Cause Code

ORNL direct	CY98	CY99	CY00	CY01	CY02
01 B d (2)			1		
02 A b			1		
02 A b					1
03 F a	1				

Savannah River
Subject Code

SRS subject	CY98	CY99	CY00	CY01	CY02
B.01.2			1		
B.04.1		1			
B.05.1		1			
B.12.1.2			1		
B.12.2			1		
C.01.3		1			
D.01		1			
E.01				1	
E.02.1		1			
E.03		1			
F.01		1			
F.06.2			1		
G.02.1		1			
L.02			1		
L.03.2			1		
P.01			1		
P.05			1		
P.06.2			1		
Q.01		1			
Q.01.1	1				
Q.03.6		1			
R.01.5			1		
R.04.1.2		1			
R.07.6	1				
S.05.2.1.1			1		
T.04.3			1		
U.01.1		1			
U.02.2.1			1		
total	**2**	**12**	**13**	**1**	

Savannah River
Direct Cause Code

SRS direct	CY98	CY99	CY00	CY01	CY02
01 B	1				
01 B d (2)		1	3		
01 B g (1)			1		
01 B g (2)		5			
01 B g (3)		1			
01 B h		1			
01 C g		1			
02 A d	1		8	1	
08 A a		1			
08 D		1			
09 B		1			
10 C			1		
total	2	12	13	1	

Savannah River
Root Cause Code

SRS root	CY98	CY99	CY00	CY01	CY02
01 C g				1	
03 A a		1			

NSNFP Suppliers

ANL-E, CTD Subject Code

ANL-E, CTD Subj. Code	CY99	CY00	CY01	CY02
A.02	1			
B.12.2.4	1			
G.11.3	1			
L.07.3	1			

ANL-E, CTD Direct Cause Code

ANL-E, CTD Direct Cause Code	CY99	CY00	CY01	CY02
01 A a	1			
02 A d	3			

ANL-W Subject Code

ANL-W Subj. Code	CY99	CY00	CY01	CY02
B.10.7		1		
E.01	1			
F.04	1			
F.05.4	1			
G.02.1	2			
Q.05	1			

ANL-W Direct Cause Code

ANL-W Direct Cause Code	CY99	CY00	CY01	CY02
01 B a	1			
01 B g (2)	2			
02 A d	2			
05 B		1		
09 B	1			

Battelle-PNNL Subject Code

Battelle Subj. Code	CY99	CY00	CY01	CY02
L.01.1	1			
Q.05.1	1			
S.01.2	1			
U.02.2.2	1			

Battelle-PNNL Direct Cause Code

Battelle Direct Cause Code	CY99	CY00	CY01	CY02
02 A d	3			
08 A b	1			

JMI Subject Code

JMI Subj. Code	CY99	CY00	CY01	CY02
B.12.2.4			1	
E.01	1		1	
S.06.3	1			

JMI Direct Cause Code

JMI Direct Cause Code	CY99	CY00	CY01	CY02
02 A			1	
02 A d	1			
03 A b			1	
08 A b	1			

LMES-OR-Y12 Subject Code

LMES Subj. Code	CY99	CY00	CY01	CY02
B.05.6	1			
B.12.2.4	1			
E.01	1			
G.02.1	1			
L.01.5	1			
L.07	1			
Q.11.1	1			

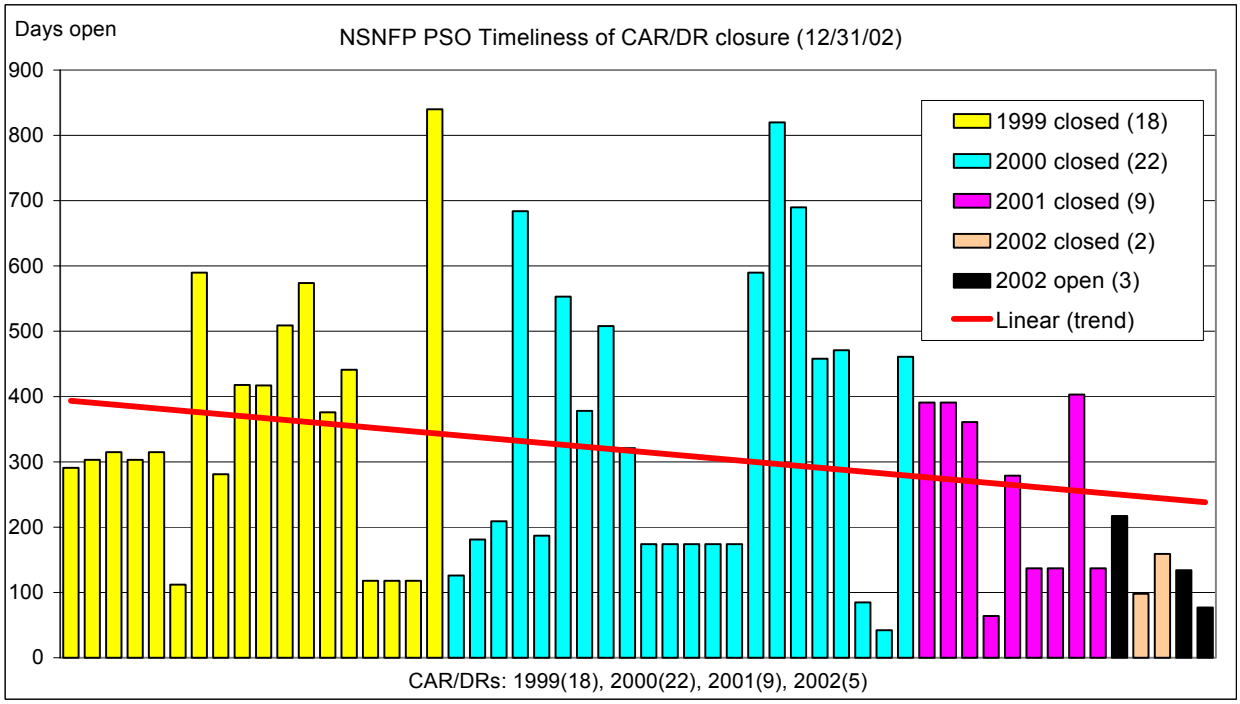
LMES-OR-Y12 Direct Cause Code

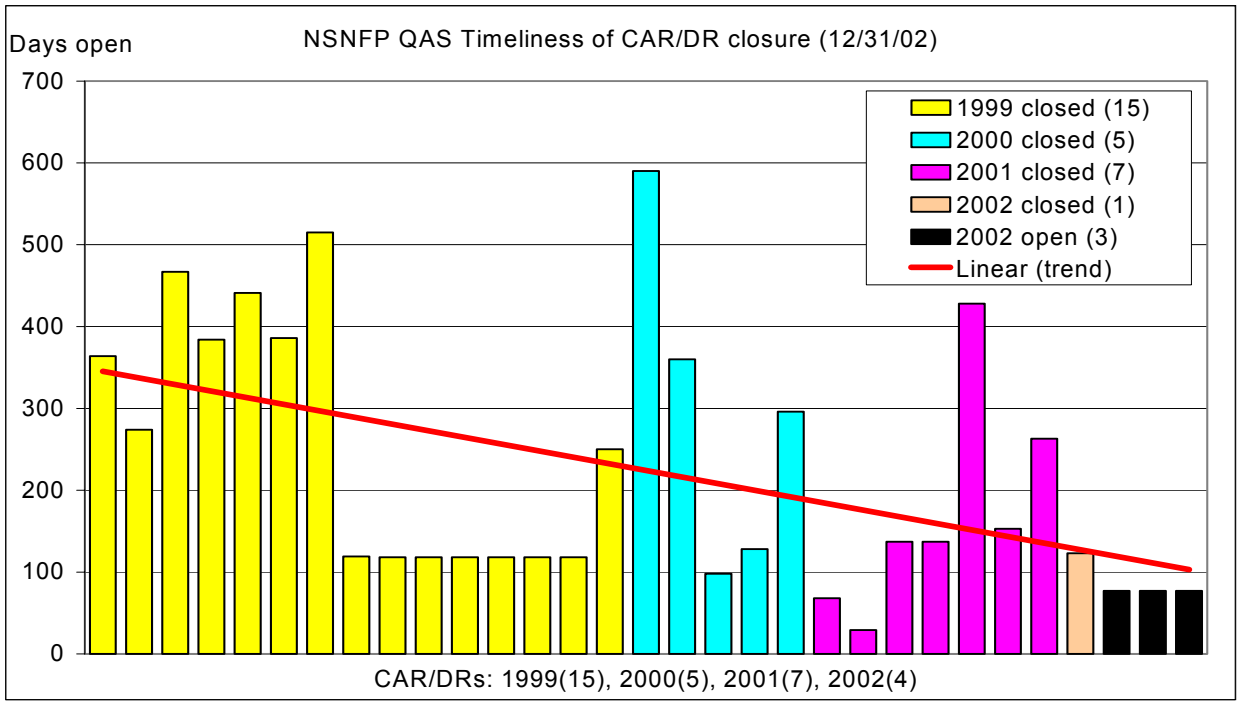
LMES Direct Cause Code	CY99	CY00	CY01	CY02
01	1			
01 A a	1			
01 A d	1			
01 B d (1)	1			
01 B g (4)	1			
02 A d	1			
09 B	1			

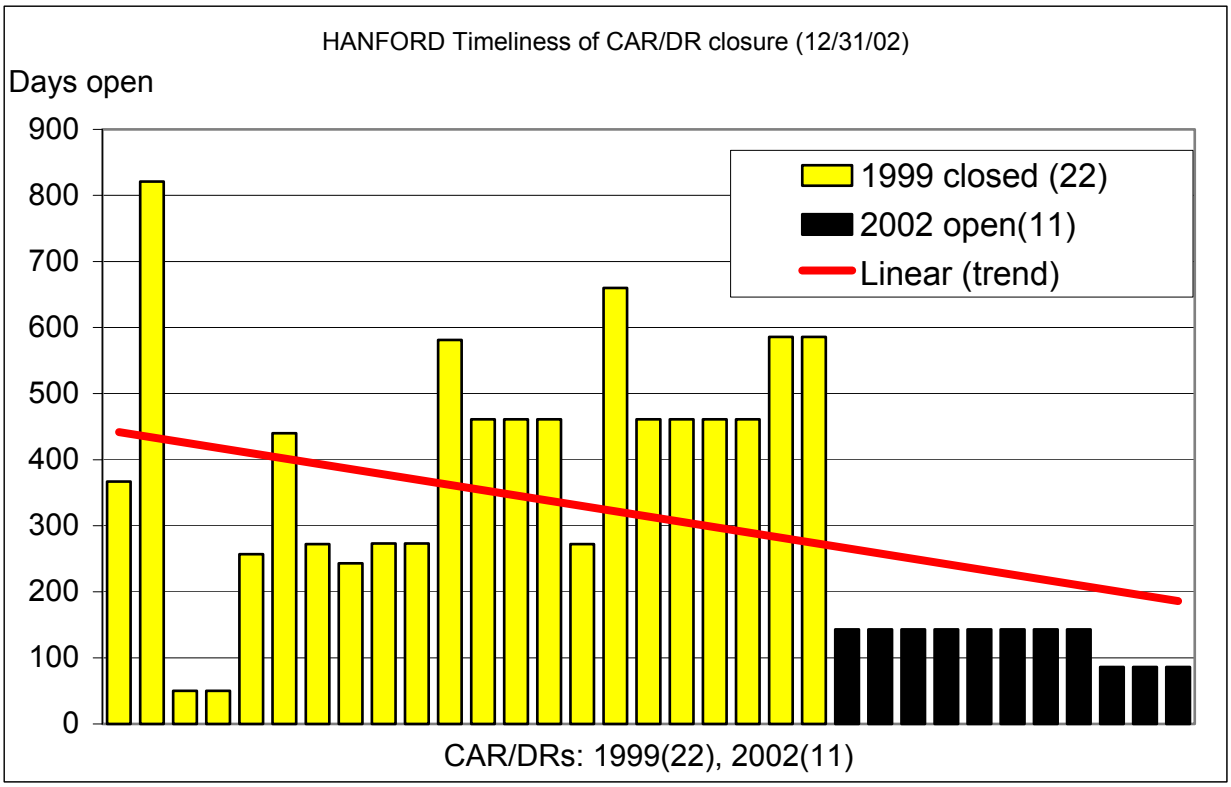
Attachment B

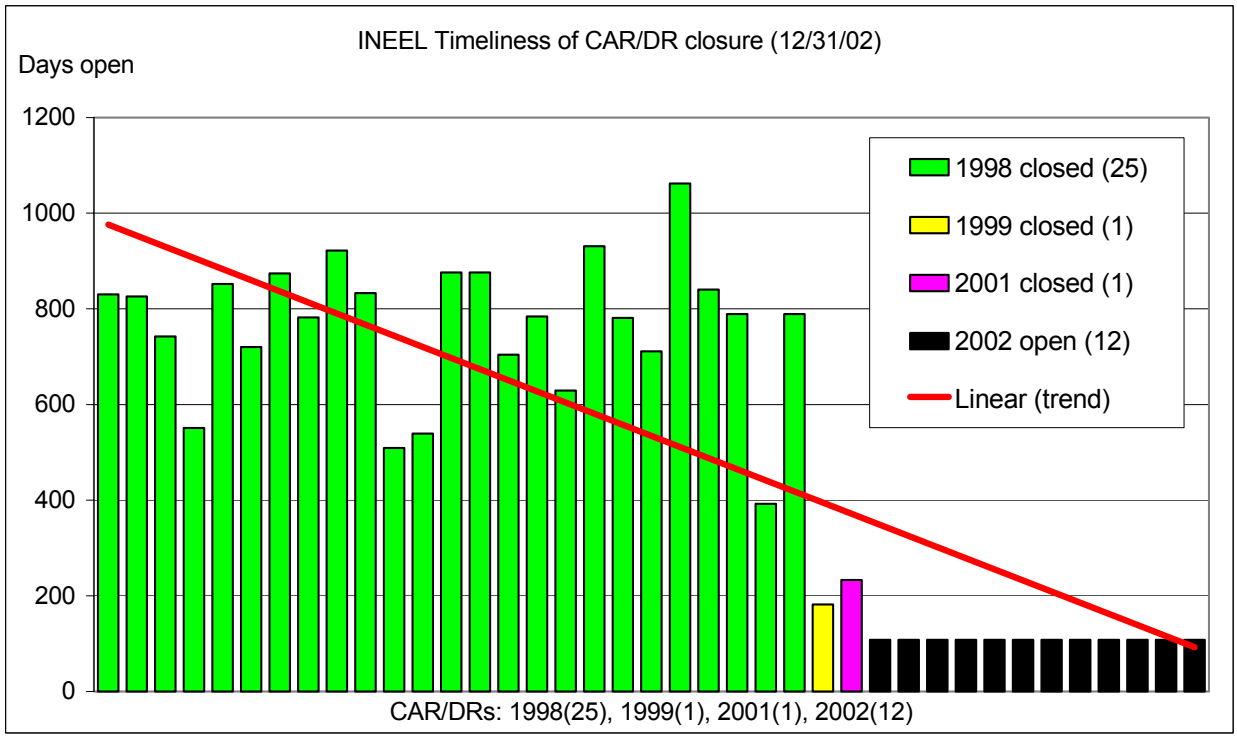
Timeliness of Deficiency Report Closure through December 31, 2002

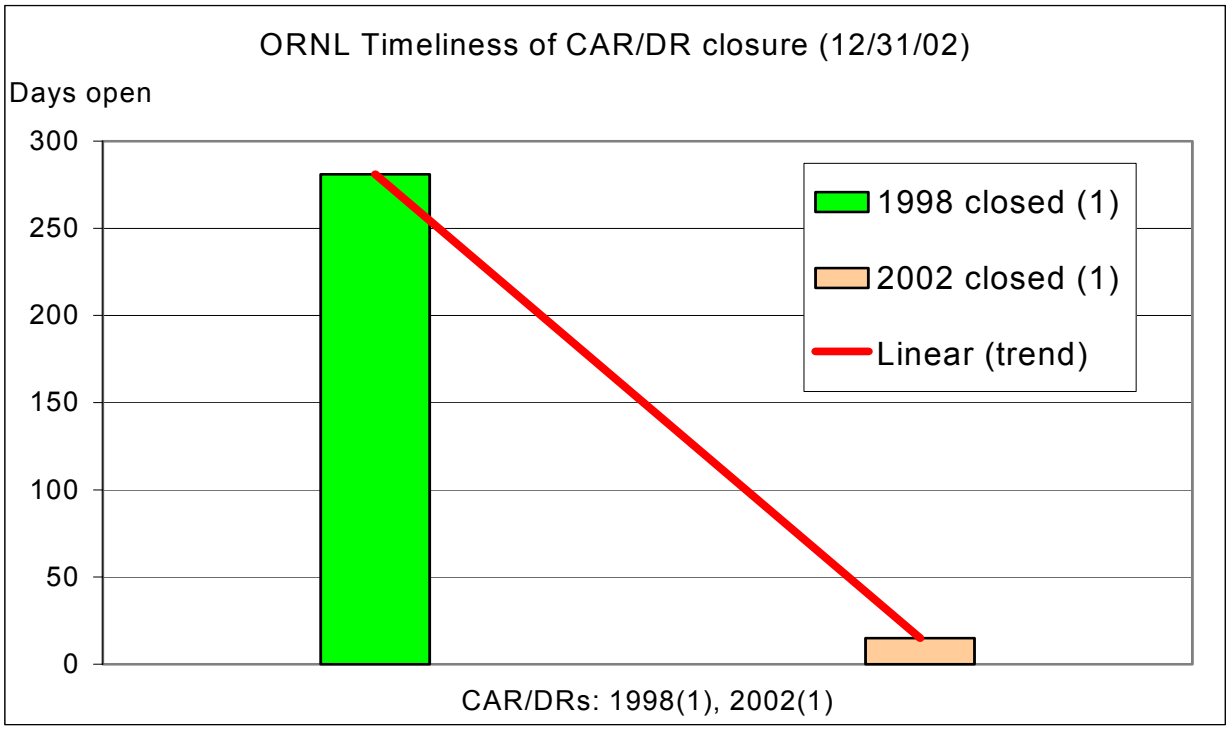
Attachment B
Timeliness of Deficiency Report Closure through December 31, 2002
(Open reports are indicated in black; CDAs closed during assessment are not shown)

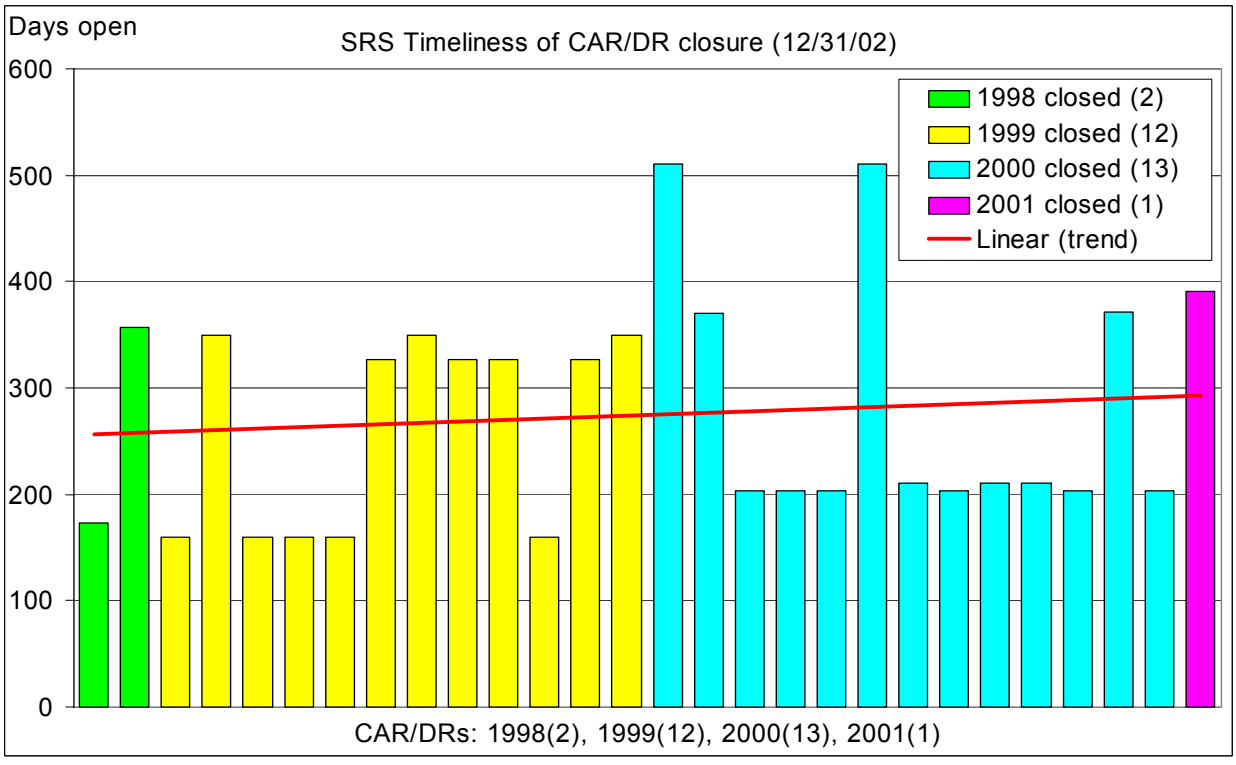





HANFORD Timeliness of CAR/DR closure (12/31/02)
Days open
900
800
700
600
500
400
300
200
100
0
1999 closed (22)
2002 open(11)
Linear (trend)
CAR/DRs: 1999(22), 2002(11)


INEEL Timeliness of CAR/DR closure (12/31/02)
Days open
1200
1000
800
600
400
200
0
1998 closed (25)
1999 closed (1)
2001 closed (1)
2002 open (12)
Linear (trend)
CAR/DRs: 1998(25), 1999(1), 2001(1), 2002(12)


ORNL Timeliness of CAR/DR closure (12/31/02)
Days open
300
250
200
150
100
50
0
1998 closed (1)
2002 closed (1)
Linear (trend)
CAR/DRs: 1998(1), 2002(1)


Days open
SRS Timeliness of CAR/DR closure (12/31/02)
600
500
400
300
200
100
0
1998 closed (2)
1999 closed (12)
2000 closed (13)
2001 closed (1)
Linear (trend)
CAR/DRs: 1998(2), 1999(12), 2000(13), 2001(1)

Attachment C

Deficiency Reports

Attachment C

Deficiency Reports

(Status February 23, 2003)

Report	Resp org	Signif	Open	Subject	Direct	Root	Close	Days	Type	Status (2/23/03)
99-NSNF-AU-039-004	ANL-E, CTD	F	04/06/99	L.07.3	02 A d		12/15/99	253	DR	closed
99-NSNF-AU-039-001	ANL-E, CTD	F	04/06/99	B.12.2.4	02 A d		10/18/99	195	DR	closed
99-NSNF-AU-039-002	ANL-E, CTD	F	04/06/99	A.02	01 A a		10/18/99	195	DR	closed
99-NSNF-AU-039-003	ANL-E, CTD	F	04/06/99	G.11.3	02 A d		10/18/99	195	DR	closed
99-NSNF-AU-058-001	ANL-W	F	07/29/99	G.02.1	09 B		02/23/00	209	DR	closed
99-NSNF-AU-058-002	ANL-W	F	07/29/99	G.02.1	02 A d		02/23/00	209	DR	closed
99-NSNF-AU-058-003	ANL-W	F	07/29/99	E.01	01 B g (2)		02/23/00	209	DR	closed
99-NSNF-AU-058-004	ANL-W	F	07/29/99	F.04	01 B g (2)		02/23/00	209	DR	closed
99-NSNF-AU-058-005	ANL-W	F	07/29/99	F.05.4	01 B a		02/23/00	209	DR	closed
99-NSNF-AU-058-006	ANL-W	F	07/29/99	Q.05	02 A d		02/23/00	209	DR	closed
00-ANLW-S-005-DR-001	ANL-W	F	04/05/00	B.10.7	05 B		06/20/00	76	DR	closed
99-NSNF-AU-036-003	Battelle-PNNL	F	01/21/99	U.02.2.2	02 A d		06/02/99	132	DR	closed
99-NSNF-AU-036-001	Battelle-PNNL	F	02/11/99	Q.05.1	02 A d		06/02/99	111	DR	closed
99-NSNF-AU-036-002	Battelle-PNNL	F	02/11/99	L.01.1	02 A d		06/02/99	111	DR	closed
99-NSNF-AU-036-004	Battelle-PNNL	F	02/11/99	S.01.2	08 A b		06/02/99	111	DR	closed
99-NSNF-S-059-01	HANFORD	F	06/15/99	B.01.3	01 B g (3)		06/16/00	367	DR	closed
99-NSNF-S-062-01	HANFORD	F	07/27/99	U.03	05 B b		10/25/01	821	DR	closed
99-NSNF-S-062-02	HANFORD	F	07/27/99	V.01	08 C		09/15/99	50	DR	closed
99-NSNF-S-062-03	HANFORD	F	07/27/99	T.01.3	02 A d		09/15/99	50	DR	closed
99-RL-MKH-001	HANFORD	TRUE	08/19/99	B.02.7	01 B g (2)		05/02/00	257	CAR	closed
99-NSNF-AU-044-I-001-R1	HANFORD	F	09/08/99	S.01.2.1	08 A b		06/29/01	660	DR	closed
99-NSNF-AU-044-V-001-R1	HANFORD	TRUE	09/08/99	V.01	08 D	03 A a	04/16/01	586	CAR	closed
99-NSNF-AU-044-III-004-R1	HANFORD	F	09/08/99	U.06.1.1	01 A a		04/16/01	586	DR	closed
99-NSNF-AU-044-2-001	HANFORD	F	09/08/99	B.01.2.1	02 A d		04/11/01	581	DR	closed
99-NSNF-AU-044-2-002	HANFORD	TRUE	09/08/99	B.09	01 B d (2)	03 A c	12/12/00	461	CAR	closed
99-NSNF-AU-044-II-001	HANFORD	TRUE	09/08/99	T.02	02 A d	01 B g (1)	12/12/00	461	CAR	closed
99-NSNF-AU-044-2-003	HANFORD	F	09/08/99	B.10.7	02 A d		12/12/00	461	DR	closed
99-NSNF-AU-044-3-001	HANFORD	F	09/08/99	C.01.3	05 A c (2)		12/12/00	461	DR	closed
99-NSNF-AU-044-III-001	HANFORD	F	09/08/99	U.01.1	05 A c (1)		12/12/00	461	DR	closed
99-NSNF-AU-044-III-002	HANFORD	F	09/08/99	U.01.2	02 A d		12/12/00	461	DR	closed
99-NSNF-AU-044-III-003	HANFORD	F	09/08/99	U.02.1	01 A a		12/12/00	461	DR	closed
99-NSNF-AU-044-10-001	HANFORD	F	09/08/99	J.07.1	01 B d (2)		11/21/00	440	DR	closed
99-NSNF-AU-044-15-001	HANFORD	F	09/08/99	O. 1.2	01 B d (2)		06/07/00	273	DR	closed
99-NSNF-AU-044-16-001	HANFORD	F	09/08/99	P.05	01 B d (2)		06/07/00	273	DR	closed
99-NSNF-AU-044-1-001	HANFORD	F	09/08/99	A.02	02 A d		06/06/00	272	DR	closed
99-NSNF-AU-044-3-002	HANFORD	F	09/08/99	C.09.1	02 A d		06/06/00	272	DR	closed
99-NSNF-AU-044-12-001	HANFORD	F	09/08/99	L.01.1	01 B g (2)		05/08/00	243	DR	closed
00-RLSNF-AU-008-CDA-001	HANFORD	F	09/11/00	P.03.3	02 A d		09/11/00	0	CDA	closed
01-HANF-AU-001-CDA-002	HANFORD	F	07/27/01	P.04.2	02 A d		07/27/01	0	CDA	closed
01-RLSNF-AU-001-CDA-002	HANFORD	F	07/27/01	P.04.2	02 A d		07/27/01	0	CDA	closed
01-HANF-AU-001-CDA-001	HANFORD	F	07/31/01	J.06.2	02 A a		07/31/01	0	CDA	closed
02-RLSNF-AU-003-DR-001	HANFORD	F	08/12/02	A.06.1	02 A b			**195**	DR	***OPEN***
02-RLSNF-AU-003-DR-003RI	HANFORD	F	08/12/02	B.01.3	02 A a			**195**	DR	***OPEN***
02-RLSNF-AU-003-DR-006R1	HANFORD	F	08/12/02	O. 1.2	01 A a			**195**	DR	***OPEN***
02-RLSNF-AU-003-DR-002	HANFORD	F	08/12/02	E.01	02 A b		02/06/03	178	DR	closed
02-RLSNF-AU-003-DR-004	HANFORD	F	08/12/02	B.10.6.3	03 A c		02/06/03	178	DR	closed
02-RLSNF-AU-003-DR-005	HANFORD	F	08/12/02	F.05.2	03 A c		02/06/03	178	DR	closed
02-RLSNF-AU-003-DR-007	HANFORD	F	08/12/02	P.06.2	02 A d		02/06/03	178	DR	closed
02-RLSNF-AU-003-DR-008	HANFORD	F	08/12/02	R.21.2.1	02 A b		02/06/03	178	DR	closed
02-RLSNF-AU-003-CDA-001	HANFORD	F	08/12/02	B.12.2.1	02 A b		08/12/02	0	CDA	closed
02-RLSNF-AU-003-CDA-002	HANFORD	F	08/12/02	E.01	02 A d		08/12/02	0	CDA	closed
02-RLSNF-AU-003-CDA-003	HANFORD	F	08/12/02	E.01	02 A d		08/12/02	0	CDA	closed
02-RLSNF-AU-003-CDA-004	HANFORD	F	08/12/02	O.04.4	04 B c		08/12/02	0	CDA	closed

Report	Resp org	Signif	Open	Subject	Direct	Root	Close	Days	Type	Status (2/23/03)
02-RLSNF-AU-001-DR-003R1	HANFORD	F	10/08/02	Q.05.1.1	01 B d (2)			138	DR	OPEN
02-RLSNF-AU-001-DR-001	HANFORD	F	10/08/02	Q.02.1	02 A d		02/06/03	121	DR	closed
02-RLSNF-AU-001-DR-002	HANFORD	F	10/08/02	Q.03.6.3	01 B d (2)		02/06/03	121	DR	closed
02-RLSNF-AU-001-CDA-001	HANFORD	F	10/08/02	B.01	01 B g (4)		10/08/02	0	CDA	closed
02-RLSNF-AU-001-CDA-002	HANFORD	F	10/08/02	B.01	01 B g (2)		10/08/02	0	CDA	closed
02-RLSNF-AU-001-CDA-003	HANFORD	F	10/08/02	C.01	01 C d		10/08/02	0	CDA	closed
02-RLSNF-AU-001-CDA-004	HANFORD	F	10/08/02	Q.05.1	01 B d (2)		10/08/02	0	CDA	closed
02-RLSNF-AU-001-CDA-005	HANFORD	F	10/08/02	Q.06.1	01 B d (2)		10/08/02	0	CDA	closed
02-RLSNF-AU-001-CDA-006	HANFORD	F	10/08/02	F.03	02 A d		10/08/02	0	CDA	closed
98-NSNF-AU-034-021	INEEL-SNF	TRUE	10/22/98	Q	01 B g (3)	01 A a	09/18/01	1062	CAR	closed
98-NSNF-AU-034-018	INEEL-SNF	F	10/22/98	M.01	01 B g (2)		05/10/01	931	DR	closed
98-NSNF-AU-034-009	INEEL-SNF	TRUE	10/22/98	B.12	04 C a	03 A c	05/01/01	922	CAR	closed
98-NSNF-AU-034-013	INEEL-SNF	TRUE	10/22/98	E.01	01 B g (2)	03 C	03/16/01	876	CAR	closed
98-NSNF-AU-034-014	INEEL-SNF	TRUE	10/22/98	F	01 B g (3)	03 A c	03/16/01	876	CAR	closed
98-NSNF-AU-034-007	INEEL-SNF	F	10/22/98	B.07	01 A a		03/14/01	874	DR	closed
98-NSNF-AU-034-005	INEEL-SNF	TRUE	10/22/98	B.05	01 B d (2)	01 B c	02/20/01	852	CAR	closed
98-NSNF-AU-034-022	INEEL-SNF	TRUE	10/22/98	R.03	01 B g (2)	03 A f	02/08/01	840	CAR	closed
98-NSNF-AU-034-010	INEEL-SNF	F	10/22/98	C	01 B e		02/01/01	833	DR	closed
98-NSNF-AU-034-001	INEEL-SNF	TRUE	10/22/98	A.02	01 B g (1)	03 A d	01/29/01	830	CAR	closed
98-NSNF-AU-034-002	INEEL-SNF	TRUE	10/22/98	B.01	01 B d (2)	03 A c	01/25/01	826	CAR	closed
98-NSNF-AU-034-025	INEEL-SNF	TRUE	10/22/98	V.01	01 B g (2)	08 C	12/19/00	789	CAR	closed
98-NSNF-AU-034-023	INEEL-SNF	F	10/22/98	B.01.2.2	08 A b		12/19/00	789	DR	closed
98-NSNF-AU-034-016	INEEL-SNF	F	10/22/98	B.01.2	01 B g (3)		12/14/00	784	DR	closed
98-NSNF-AU-034-008	INEEL-SNF	F	10/22/98	B.11	01 A a		12/12/00	782	DR	closed
98-NSNF-AU-034-019	INEEL-SNF	TRUE	10/22/98	O.01	01 B d (2)	03 A c	12/11/00	781	CAR	closed
98-NSNF-AU-034-003	INEEL-SNF	TRUE	10/22/98	B.02	01 B g (2)	03 A c	11/02/00	742	CAR	closed
98-NSNF-AU-034-006	INEEL-SNF	F	10/22/98	B.06	02 A d		10/11/00	720	DR	closed
98-NSNF-AU-034-020	INEEL-SNF	TRUE	10/22/98	P	01 B g (2)	03 A f	10/02/00	711	CAR	closed
98-NSNF-AU-034-015	INEEL-SNF	F	10/22/98	G.06.3.4	01 B g (2)		09/25/00	704	DR	closed
98-NSNF-AU-034-017	INEEL-SNF	TRUE	10/22/98	L.01.6	01 B g (2)	03 A c	07/12/00	629	CAR	closed
98-NSNF-AU-034-004	INEEL-SNF	F	10/22/98	B.05	02 A d		04/25/00	551	DR	closed
98-NSNF-AU-034-012	INEEL-SNF	F	10/22/98	B.01.2	01 B g (2)		04/13/00	539	DR	closed
98-NSNF-AU-034-011	INEEL-SNF	F	10/22/98	B.01.3	01 B d (2)		03/14/00	509	DR	closed
98-NSNF-AU-034-024	INEEL-SNF	TRUE	10/22/98	B.01.2	01 B g (2)	03 A b	11/18/99	392	CAR	closed
99-NSNF-S-051-001	INEEL-SNF	F	06/21/99	R.06.3	02 A d		12/20/99	182	DR	closed
01-INEEL-S-005-DR-001	INEEL-SNF	F	05/01/01	B.12.1.4	02 A		12/20/01	233	DR	closed
02-INEEL-AU-001-CDA-004	INEEL-SNF	F	06/16/02	C.05.1	02 A a		09/16/02	92	CDA	closed
02-INEEL-AU-001-DR-007	INEEL-SNF	F	09/16/02	P.03.2	03 A c			160	DR	OPEN
02-INEEL-AU-001-DR-009	INEEL-SNF	F	09/16/02	L.03.2.1	02 A b			160	DR	OPEN
02-INEEL-AU-001-DR-010	INEEL-SNF	F	09/16/02	L.03.2.2.1	03 A f			160	DR	OPEN
02-INEEL-AU-001-DR-011	INEEL-SNF	F	09/16/02	M.01.1	01 B g (2)			160	DR	OPEN
02-INEEL-AU-001-DR-001	INEEL-SNF	F	09/16/02	B.11.2	01 D		02/04/03	141	DR	closed
02-INEEL-AU-001-DR-002	INEEL-SNF	F	09/16/02	B.01.3.1.1	03 A c		02/04/03	141	DR	closed
02-INEEL-AU-001-DR-003	INEEL-SNF	F	09/16/02	Q.02.1.1	01 B d (2)		02/04/03	141	DR	closed
02-INEEL-AU-001-DR-004	INEEL-SNF	F	09/16/02	B.01.2.1	10 C		02/04/03	141	DR	closed
02-INEEL-AU-001-DR-005, Rev. 1	INEEL-SNF	F	09/16/02	E.01	03 A c		02/04/03	141	DR	closed
02-INEEL-AU-001-DR-006	INEEL-SNF	F	09/16/02	O.03.1	02 A a		02/04/03	141	DR	closed
02-INEEL-AU-001-DR-008	INEEL-SNF	F	09/16/02	P.03.2	03 A f		02/04/03	141	DR	closed
02-INEEL-AU-001-CDA-001	INEEL-SNF	F	09/16/02	K.01.4	02 A b		09/16/02	0	CDA	closed
02-INEEL-AU-001-CDA-002	INEEL-SNF	F	09/16/02	Q.03.4	02 A b		09/16/02	0	CDA	closed
02-INEEL-AU-001-CDA-003	INEEL-SNF	F	09/16/02	Q.05.1	02 A d		09/16/02	0	CDA	closed
02-INEEL-AU-001-CDA-005	INEEL-SNF	F	09/16/02	N.01.1	03 A c		09/16/02	0	CDA	closed
02-SUPP-S-007-CDA-001	INEEL-SNF	F	11/13/02	E.01	01 B a		11/13/02	0	CDA	closed
99-NSNF-S-064-001	JMI	F	08/10/99	S.06.3	08 A b		03/21/00	224	DR	closed
99-NSNF-S-064-002	JMI	F	08/10/99	E.01	02 A d		03/21/00	224	DR	closed
01-JMI-AU-004-CDA-001	JMI	F	10/04/01	B.12.2.4	02 A		10/04/01	0	CDA	closed
01-JMI-AU-004-DR-001	JMI	F	10/05/01	E.01	03 A b		06/24/02	262	DR	closed
99-NSNF-AU-035-001	LMES-OR-Y12	F	12/23/98	B.12.2.4	01		03/18/99	85	DR	closed
99-NSNF-AU-035-002	LMES-OR-Y12	F	12/23/98	G.02.1	01 B d (1)		03/18/99	85	DR	closed
99-NSNF-AU-035-003	LMES-OR-Y12	F	12/23/98	L.07	09 B		03/18/99	85	DR	closed
99-NSNF-AU-035-004	LMES-OR-Y12	F	12/23/98	L.01.5	01 A d		03/18/99	85	DR	closed

Report	Resp org	Signif	Open	Subject	Direct	Root	Close	Days	Type	Status (2/23/03)
99-NSNF-AU-035-005	LMES-OR-Y12	F	12/23/98	E.01	01 A a		03/18/99	85	DR	closed
99-NSNF-AU-035-006	LMES-OR-Y12	F	12/23/98	Q.11.1	02 A d		03/18/99	85	DR	closed
99-NSNF-AU-035-007	LMES-OR-Y12	F	12/23/98	B.05.6	01 B g (4)		03/18/99	85	DR	closed
99-NSNF-QAMA-001	NSNF QA	TRUE	07/20/99	A.03	03 F a	03 A	07/18/00	364	CAR	closed
EKO-QAT-9901	NSNF QA	F	08/17/99	P.06.3	08 D		05/17/00	274	DR	closed
99-NSNF-AU-125-003	NSNF QA	F	09/01/99	Q.02	02 A d		12/11/00	467	DR	closed
99-NSNF-AU-125-006	NSNF QA	F	09/01/99	B.01.3.1.1	03 A c		11/15/00	441	DR	closed
99-NSNF-AU-125-007	NSNF QA	F	09/01/99	E.05	02 A d		09/21/00	386	DR	closed
99-NSNF-AU-125-005	NSNF QA	F	09/01/99	B.12	01 B g (2)		09/19/00	384	DR	closed
99-NSNF-FSV-CK-002	NSNF QA	F	09/17/99	E.03.2	01 B g (2)		02/13/01	515	DR	closed
99-ARC-04-9/99-011/RW CAR #C-005	NSNF QA	TRUE	10/07/99	Q.02.2	02 A d	02 A	06/13/00	250	CAR	closed
99-ARC04-9/99-001/RW DR#D-083	NSNF QA	F	10/07/99	E.01	02 A d		02/03/00	119	DR	closed
99-ARC04-9/99-003/RW DR#D-085	NSNF QA	F	10/07/99	E.03	02 A d		02/02/00	118	DR	closed
99-ARC04-9/99-005/RW DR#D-087	NSNF QA	F	10/07/99	E.01	02 A d		02/02/00	118	DR	closed
99-ARC04-9/99-006/RW DR#D-088	NSNF QA	F	10/07/99	E.01	02 A d		02/02/00	118	DR	closed
99-ARC04-9/99-007/RW DR#D-089	NSNF QA	F	10/07/99	F.07.2.2	01 B d (2)		02/02/00	118	DR	closed
99-ARC04-9/99-008/RW DR #D-090	NSNF QA	F	10/07/99	R.08.5	02 A d		02/02/00	118	DR	closed
99-ARC04-9/99-009/RW DR#D-091	NSNF QA	F	10/07/99	E.01	02 A d		02/02/00	118	DR	closed
00-NSNF-AU-011-DR-005	NSNF QA	F	06/19/00	P.03.2	03 A f		01/30/02	590	DR	closed
00-RW-08/31/00-DR-002	NSNF QA	F	10/17/00	B.01.2.4	03 A d		10/12/01	360	DR	closed
00-RW-08/31/00-DR-006	NSNF QA	F	10/17/00	R.01.6	03 A d		08/09/01	296	DR	closed
00-RW-08/31/00-DR-005	NSNF QA	F	10/17/00	P.06.2	01 B g (2)		02/22/01	128	DR	closed
00-RW-08/31/00-DR-004	NSNF QA	F	10/17/00	Q.03.7	02 A d		01/23/01	98	DR	closed
01-NSNF-S-006-CDA-001	NSNF QA	F	12/18/00	Q.02.2	02 A d		12/18/00	0	CDA	closed
01-NSNF-S-006-DR-002	NSNF QA	F	01/24/01	B.12.1.2	01 B g (4)		04/02/01	68	DR	closed
01-NSNF-S-006-DR-003	NSNF QA	F	01/24/01	E.01	02 A d		02/22/01	29	DR	closed
01-NSNFP-AU-001-CDA-002	NSNF QA	F	09/06/01	B.01.3.3	01 B d (1)		09/06/01	0	CDA	closed
01-NSNFP-AU-001-DR-005	NSNF QA	F	09/17/01	G.03.4	02 A d		11/19/02	428	DR	closed
01-NSNFP-AU-001-DR-002	NSNF QA	F	09/17/01	B.01.2.1	02 A d		02/01/02	137	DR	closed
01-NSNFP-AU-001-DR-003	NSNF QA	F	09/17/01	E.01	02 A d		02/01/02	137	DR	closed
RW EM-01-D-145	NSNF QA	F	10/04/01	P.04.2	03 B a		06/24/02	263	DR	closed
RW EM-01-D-144	NSNF QA	F	10/04/01	R.01.1	01 C f		03/06/02	153	DR	closed
02-NSNF-AU-001-DR-001	NSNF QA	F	05/30/02	A.03.2	01 C		09/30/02	123	DR	closed
02-NSNF-AU-001-CDA-003	NSNF QA	F	05/30/02	B.01.1	03 A		05/30/02	0	CDA	closed
EM-ARC-02-10/ EM(0)-03-D-004	NSNF QA	F	10/17/02	U.06.3.2	01 A a			**129**	DR	***OPEN***
EM-ARC-02-10/ EM(0)-03-D-005	NSNF QA	F	10/17/02	G.06.3.4	02 A d		01/09/03	84	DR	closed
EM-ARC-02-10/ EM(0)-03-D-007	NSNF QA	F	10/17/02	P.04.5.2	02 A d		01/09/03	84	DR	closed
03-NSNF-S-001-CDA-001	NSNF QA	F	12/06/02	B.12.1.2	02 A c		12/06/02	0	CDA	closed
99-NSNF-S-127-04	NSNFP	TRUE	06/28/99	V.01	01 A a	03 D	02/07/01	590	CAR	closed
99-NSNF-S-123-003	NSNFP	F	06/28/99	E.01	02 A d		05/08/00	315	DR	closed
99-NSNF-S-127-02	NSNFP	F	06/28/99	S.02	08 A b		05/08/00	315	DR	closed
99-NSNF-S-123-002	NSNFP	TRUE	06/28/99	C.04.5.1.3	01 B d (2)	03 A c	04/26/00	303	CAR	closed
99-NSNF-S-127-01	NSNFP	F	06/28/99	B.03	01 B f		04/26/00	303	DR	closed
99-NSNF-S-123-001	NSNFP	F	06/28/99	B.03	01 B d (2)		04/14/00	291	DR	closed
99-NSNF-S-127-03	NSNFP	F	06/28/99	B.10.6.3	01 C f		10/18/99	112	DR	closed
99-NSNF-QAMA-002	NSNFP	TRUE	07/20/99	C.01.4	05 A b	03 A c	04/26/00	281	CAR	closed
99-NSNF-AU-125-001	NSNFP	TRUE	07/21/99	D.01.3.1.1	01 B g (3)	03 A a	09/11/00	418	CAR	closed
99-NSNF-AU-125-004	NSNFP	F	07/22/99	B.01.2.3	01 B g (4)		09/11/00	417	DR	closed
99-NSNF-S-126-002	NSNFP	F	07/29/99	D.01.2.3	02 A d		02/22/01	574	DR	closed
99-NSNF-S-126-001	NSNFP	F	07/29/99	E.01	02 A d	03 D	12/19/00	509	DR	closed
99-NSNF-AU-125-008	NSNFP	F	09/01/99	D.01.2.3	01 B		11/15/00	441	DR	closed
99-NSNF-AU-125-002	NSNFP	TRUE	09/01/99	D.01.3.3.1	01 B g (1)	03 A a	09/11/00	376	CAR	closed
99-ARC04-9/99-002/RW DR#D-084	NSNFP	F	10/07/99	C.02.1	02 A d		02/02/00	118	DR	closed
99-ARC04-9/99-004/RW DR#D-086	NSNFP	F	10/07/99	B.12.1	01 B d (2)		02/02/00	118	DR	closed
99-ARC04-9/99-010/RW DR#D-092	NSNFP	F	10/07/99	S.06.1.1	01 B g (3)		02/02/00	118	DR	closed
99-NSNF-S-132-001	NSNFP	TRUE	10/12/99	G.02.1	01 B	01 B h	01/29/02	840	CAR	closed
00-NSNF-S-005-001	NSNFP	TRUE	01/31/00	B.03	02 A		06/05/00	126	CAR	closed
00-NSNF-S-003-1	NSNFP	F	02/24/00	D.01.6	05 B a		08/23/00	181	DR	closed
00-NSNF-S-008-DR-001	NSNFP	F	03/16/00	E.01	02 A d		10/11/00	209	DR	closed
00-NSNFP-03/13-DR-001	NSNFP	F	03/17/00	F.07.1.1	02 A d		01/30/02	684	DR	closed
00-NSNFP-S-018-DR-001	NSNFP	F	03/31/00	B.12.1.2	01 B g (2)		10/04/00	187	DR	closed
00-NSNFP-S-009-DR-001	NSNFP	F	04/27/00	S.01.1	02 A d		11/01/01	553	DR	closed

Report	Resp org	Signif	Open	Subject	Direct	Root	Close	Days	Type	Status (2/23/03)
00-NSNF-S-009-DR-003	NSNFP	F	04/27/00	S.01.1	01 B g (2)		09/17/01	508	DR	closed
00-NSNF-S-009-DR-002	NSNFP	F	04/27/00	S.06.2.2	01 B g (4)		05/10/01	378	DR	closed
00-NSNFP-05/09-DR-001	NSNFP	F	05/11/00	S.07	08 A c		03/28/01	321	DR	closed
00-SUPP-AU-009-DR-001	NSNFP	F	06/07/00	E.01	01 B		11/28/00	174	DR	closed
00-SUPP-AU-009-DR-002	NSNFP	F	06/07/00	B.12.1.2	01 B		11/28/00	174	DR	closed
00-SUPP-AU-009-DR-003	NSNFP	F	06/07/00	D.01.3.3.2	01 B		11/28/00	174	DR	closed
00-SUPP-AU-009-DR-004	NSNFP	F	06/07/00	A.02	01 B		11/28/00	174	DR	closed
00-SUPP-AU-009-DR-005	NSNFP	F	06/07/00	J.09.1	01 B		11/28/00	174	DR	closed
00-NSNF-AU-011-DR-002	NSNFP	F	06/19/00	B.01.2	02 A d		09/17/02	820	DR	closed
00-NSNF-AU-011-DR-003	NSNFP	F	06/19/00	B.12.1	01 B g (4)		05/10/02	690	DR	closed
00-NSNF-AU-011-DR-001	NSNFP	F	06/19/00	A.01	01 B		01/30/02	590	DR	closed
00-NSNF-AU-011-DR-004	NSNFP	F	06/19/00	D.01	02 A		09/20/01	458	DR	closed
00-NSNF-S-006-CDA-001	NSNFP	F	10/03/00	Q.02.2	02 A d		10/03/00	0	CDA	closed
00-NSNF-S-006-DR-001	NSNFP	F	10/17/00	E.03.1	01 A a		01/31/02	471	DR	closed
00-RW-08/31/00-DR-001	NSNFP	F	10/17/00	R.02.6	01 B g (2)		01/10/01	85	DR	closed
00-RW-08/31/00-DR-003	NSNFP	F	10/17/00	F.05.3	01 B g (2)		11/28/00	42	DR	closed
01-NSNF-S-004-DR-001	NSNFP	F	12/19/00	C.01.4	02 A d		03/25/02	461	DR	closed
01-NSNF-S-004-CDA-001	NSNFP	F	12/19/00	B.12.1.4	02 A d		12/19/00	0	CDA	closed
01-QAMA-9/18-DR-001	NSNFP	F	01/05/01	B.01.2.1	10 A		01/31/02	391	DR	closed
01-QAMA-9/18-DR-002	NSNFP	F	01/05/01	B.12.2	10 A		01/31/02	391	DR	closed
01-NSNF-S-002-DR-001	NSNFP	F	01/21/01	F.05.4	10 C		01/17/02	361	DR	closed
01-NSNF-S-006-DR-001	NSNFP	F	01/24/01	F.05.1	01 B g (4)		03/29/01	64	DR	closed
01-NSNF-S-009-CDA-001	NSNFP	F	04/26/01	Q.05.1.1	02 A d		04/26/01	0	CDA	closed
01-NSNF-S-009-CDA-002	NSNFP	F	04/26/01	Q.02.2	02 A d		04/26/01	0	CDA	closed
01-NSNF-S-009-DR-001	NSNFP	F	05/03/01	Q.08.1.1	01 B g (4)		02/06/02	279	DR	closed
01-NSNFP-AU-001-CDA-001	NSNFP	F	09/05/01	A.03.2.6	01 B d (1)		09/05/01	0	CDA	closed
01-NSNFP-AU-001-DR-006	NSNFP	F	09/17/01	B.01.2	02 A d		10/25/02	403	DR	closed
01-NSNFP-AU-001-DR-001	NSNFP	F	09/17/01	A.01	02 A d		02/01/02	137	DR	closed
01-NSNFP-AU-001-DR-004	NSNFP	F	09/17/01	E.01	02 A d		02/01/02	137	DR	closed
01-NSNFP-AU-001-DR-007	NSNFP	F	09/17/01	E.01	02 A d		02/01/02	137	DR	closed
02-NSNF-S-001-CDA-001	NSNFP	F	01/22/02	G.06.3.5	02 A a		01/22/02	0	CDA	closed
02-NSNF-AU-001-CAR-001	NSNFP	TRUE	05/30/02	G.02.1	01 C	03 A f	01/09/03	224	CAR	closed
02-NSNF-AU-001-DR-003	NSNFP	F	05/30/02	B.06	03 A		11/05/02	159	DR	closed
02-NSNF-AU-001-DR-002	NSNFP	F	05/30/02	A.03.2.1	01 B		09/05/02	98	DR	closed
02-NSNF-AU-001-CDA-001	NSNFP	F	05/30/02	K.05.3	02 A b		05/30/02	0	CDA	closed
02-NSNF-AU-001-CDA-002	NSNFP	F	05/30/02	E.05	01 C		05/30/02	0	CDA	closed
02-NSNF-AU-001-CAR-002, Rev. 1	NSNFP	TRUE	08/21/02	A.03.2.1	03 A d	03 A d	01/09/03	141	CAR	closed
02-SUPP-S-006-CDA-001	NSNFP	F	10/08/02	F.05.3	02 A b		10/08/02	0	CDA	closed
EM-ARC-02-10/ EM(0)-03-D-006	NSNFP	F	10/17/02	V.01.3	01 A a			**129**	DR	***OPEN***
98-NSNF-AU-120-001	OAK RIDGE	F	12/23/98	R.01.5	03 F a		09/30/99	281	DR	closed
01-ORNL-AU-001-CDA-02	OAK RIDGE	F	12/07/00	R.21.2.1	02 A b		12/07/00	0	CDA	closed
01-ORNL-AU-001-CDA-1	OAK RIDGE	F	12/07/00	Q.01.1.7	01 B d (2)		12/07/00	0	CDA	closed
02-ORNL-AU-001-DR-001	OAK RIDGE	F	09/18/02	F.06.2	02 A b		10/03/02	15	DR	closed
98-NSNF-S-033-2	SRS	F	09/17/98	R.07.6	02 A d		03/09/99	173	DR	closed
98-NSNF-S-033-1	SRS	F	10/05/98	Q.01.1	01 B		09/27/99	357	DR	closed
99-NSNF-AU-068-4	SRS	TRUE	09/16/99	D.01	01 B g (2)	03 A a	08/30/00	349	CAR	closed
99-NSNF-AU-068-10	SRS	F	09/16/99	Q.03.6	08 D		08/30/00	349	DR	closed
99-NSNF-AU-068-9	SRS	F	09/16/99	Q.01	08 A a		08/30/00	349	DR	closed
99-NSNF-AU-068-3	SRS	F	09/16/99	C.01.3	01 B g (2)		08/08/00	327	DR	closed
99-NSNF-AU-068-5	SRS	F	09/16/99	E.02.1	01 B h		08/08/00	327	DR	closed
99-NSNF-AU-068-6	SRS	F	09/16/99	E.03	01 B g (2)		08/08/00	327	DR	closed
99-NSNF-AU-068-8	SRS	F	09/16/99	G.02.1	09 B		08/08/00	327	DR	closed
99-NSNF-AU-068-1	SRS	F	09/16/99	B.04.1	01 B d (2)		02/23/00	160	DR	closed
99-NSNF-AU-068-11	SRS	F	09/16/99	R.04.1.2	01 C g		02/23/00	160	DR	closed
99-NSNF-AU-068-12	SRS	F	09/16/99	U.01.1	01 B g (2)		02/23/00	160	DR	closed
99-NSNF-AU-068-2	SRS	F	09/16/99	B.05.1	01 B g (2)		02/23/00	160	DR	closed
99-NSNF-AU-068-7	SRS	F	09/16/99	F.01	01 B g (3)		02/23/00	160	DR	closed
01-SRS-AU-001-DR-1	SRS	F	11/08/00	B.12.1.2	02 A d		04/02/02	510	DR	closed
01-SRS-AU-001-DR-2	SRS	F	11/08/00	B.12.2	02 A d		04/02/02	510	DR	closed
01-SRS-AU-001-DR-8	SRS	F	11/08/00	P.01	01 B d (2)		11/14/01	371	DR	closed
01-SRS-AU-001-DR-10	SRS	F	11/08/00	R.01.5	02 A d		11/13/01	370	DR	closed
01-SRS-AU-001-DR-3	SRS	F	11/08/00	B.01.2	02 A d		06/06/01	210	DR	closed

Report	Resp org	Signif	Open	Subject	Direct	Root	Close	Days	Type	Status (2/23/03)
01-SRS-AU-001-DR-5	SRS	F	11/08/00	L.03.2	02 A d		06/06/01	210	DR	closed
01-SRS-AU-001-DR-6	SRS	F	11/08/00	L.02	02 A d		06/06/01	210	DR	closed
01-SRS-AU-001-DR-11	SRS	F	11/08/00	S.05.2.1.1	02 A d		05/30/01	203	DR	closed
01-SRS-AU-001-DR-12	SRS	F	11/08/00	T.04.3	02 A d		05/30/01	203	DR	closed
01-SRS-AU-001-DR-13	SRS	F	11/08/00	U.02.2.1	01 B d (2)		05/30/01	203	DR	closed
01-SRS-AU-001-DR-4	SRS	F	11/08/00	F.06.2	10 C		05/30/01	203	DR	closed
01-SRS-AU-001-DR-7	SRS	F	11/08/00	P.06.2	01 B g (1)		05/30/01	203	DR	closed
01-SRS-AU-001-DR-9	SRS	F	11/08/00	P.05	01 B d (2)		05/30/01	203	DR	closed
01-SRS-02/22/01-CAR-001	SRS	TRUE	03/07/01	E.01	02 A d	01 C g	04/02/02	391	CAR	closed

General Notes

Report Identification of Deficiency Report, Corrective Action Report, or Condition Corrected during Audit.

Resp Org Organization responsible for correcting the condition.

Signif Significant condition adverse to quality as defined by procedure QAS 16.02.

Open Date of NSNFP QAPM approval for issuance.

Subject Subject code based on the QARD requirement violated. Attachment D of this report lists the subject codes and QARD requirements.

Direct Direct cause code based on the direct cause of the condition identified in the report. Attachment E lists the cause codes used by QAS 16.03.

Root (For CARs only) Root cause code based on the root cause of the condition identified in the report. Attachment E lists the cause codes used by QAS 16.03.

Close Date of NSNFP QAPM approval for closure. The closure status in this table is shown as of February 23, 2003 and identifies report closures in 2003. Note that the trending figures in Attachment B were based on the closure status through December 31, 2002.

Days Duration in number of days the deficiency report remains open, computed as the difference between the open and closure dates. For open reports, the duration shown in this table is computed as the difference between the open date and February 23, 2003. Note that the trending figures in Attachment B were based on the duration in days through December 31, 2002.

Type Identifies the type of deficiency:
DR denotes a deficiency report for a condition adverse to quality
CAR denotes a significant condition adverse to quality
CDA denotes a condition corrected during the audit or surveillance.

Status Identifies the status of the deficiency as of February 23, 2003, to recognize work in progress at the time this trending report was prepared. For the purposes of the analysis and trending, the data were evaluated based on the status at the end of the calendar year (December 31, 2002).

Attachment D

Subject Codes

Attachment D
Subject Codes

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	CODE
Section 1	ORGANIZATION	**A**
1.2	REQUIREMENTS Each Affected Organization shall prepare one or more controlled documents, accepted by the OCRWM Office of Quality Assurance that describes internal and external organizational interfaces, organizational structures, requirements, and responsibilities for its scope of work.	A.1
1.2.1	Line Management Each Affected Organization shall identify the responsibilities and authorities of those organizations and management positions responsible for achieving and maintaining quality.	A.2
  1.2.2.:1s	Quality Assurance Management The Director, Office of Quality Assurance, is the management position responsible for performing the QA function for the OCRWM Program; authority to execute this responsibility may be delegated to the Affected Organization.	A.3 A.3.1
1.2.2.:2s	This position shall be occupied by an individual with appropriate knowledge and experience in management and QA.	A.3.2
1.2.2A.	The position shall: A.Be at the same or higher organization level as the highest line manager directly responsible for performing work subject to the QA Requirements and Description (QARD).	A.3.2.1
1.2.2B.	B.Be sufficiently independent from cost and schedule considerations.	A.3.2.2
1.2.2C.	C.Have the organizational freedom to effectively communicate with other senior management positions.	A.3.2.3
1.2.2D.	D.Be responsible for interpreting and approving QA program requirements.	A.3.2.4
1.2.2E.	E.Have no other assigned responsibilities unrelated to the QA program that would prevent full attention to QA matters.	A.3.2.5
1.2.2F.	F.Be responsible for identifying quality problems, initiating, recommending, or providing solutions to quality problems. and verifying solutions to quality problems.	A.3.2.6
1.2.2G.	G.Be responsible for verifying the proper establishment and execution of the QA program.	A.3.2.7
1.2.2H.	H.Have the authority to stop work when significant conditions adverse to quality warrant such action.	A.3.2.8
1.2.3 1.2.3.:1s	Responsibility for Quality Quality shall be achieved and maintained by those who have been assigned responsibility for performing work.	A.4 A.4.1
1.2.3.:2s	Quality achievement shall be verified by persons or organizations not directly responsible for performing the work.	A.4.2
1.2.4 1.2.4.:1s	Delegation of Work Positions or organizations responsible for establishing and executing the QA program may delegate work to other organizations.	A.5 A.5.1
1.2.4.:2s	The positions or organizations making the delegation shall retain overall responsibility for the delegated work.	A.5.2
1.2.5	Resolution of Quality Disputes Differences of opinion involving QA program requirements shall be brought to the attention of the appropriate management and, if not resolved, shall be elevated progressively to successively higher levels of management.	A.6 A.6.1
1.3 1.3.1 1.3.2	1.3Description 1.3.1General Description of the Office of Civilian Radioactive Waste Management (OCRWM) Specific Civilian Radioactive Waste Management Offices	 A.7 A.8
1.3.3	1.3.3Other OCRWM Affected Organizations	A.9
Section 2	QUALITY ASSURANCE PROGRAM	B
2.2 2.21 2.2.1A.	REQUIREMENTS Quality Assurance Program Documents A.Affected Organizations shall issue a policy statement signed by senior line management directing mandatory compliance with this QA program.	 B.1 B.1.1
2.2.1B.:1s	B.Affected Organizations shall establish implementing documents applicable to their scope of work that translate QARD requirements into work processes.	B.1.2
2.2.1B.1.	The following requirements apply to implementing documents. 1.Each Affected Organization shall establish a structured system of implementing documents that provides for top down implementation of the QARD or, if stipulated in procurement documents, shall work to the implementing documents of another Affected Organization.	B.1.2.1
2.2.1B.2.	2.The system shall accommodate the size and location(s) of the organization, the organizational structure, and the nature of the work such that management processes will be carried out efficiently and effectively.	B.1.2.2
2.2.1B.3.	3.The system shall provide positive control over external interfaces between Affected Organizations and internal interfaces within an organization.	B.1.2.3
2.2.1B.4.	4.Each Affected Organization shall review revisions to the QARD and incorporate changes into their implementing documents, as appropriate.	B.1.2.4
2.2.1C.	C.Each Affected Organization shall complete a QARD requirements matrix for the portion of the QARD which they are implementing.	B.1.3

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2.2.1C.1.a.	1.The matrix shall identify: a.Where the QARD requirements are directly addressed.	B.1.3.1 B.1.3.1
2.2.1C.1.b.	b.Where QARD requirements are not applicable based on scope of work.	B.1.3.2
2.2.1C.1.c.	c.Where exceptions to QARD requirements have been taken including justification.	B.1.3..3
2.2.1C.2.	2.Initial QARD requirements matrices shall be reviewed by OQA in accordance with QARD Subsection 2.2.10, Document Review.	B.1.3.2
2.2.1C.3.	3.As changes are made to implementing documents each Affected Organization shall ensure that respective QARD requirements matrices are revised if necessary.	B.1.3.3
2.2.1C.4.	4.Changes to QARD requirements matrices shall be reviewed by the QA organization in accordance with Subsection 2.2.10,	B.1.3.4
2.2.2	The QA program shall apply to the following, which shall be included on a Q-List.	B.2
2.2.2A.	A.Items important to public radiological safety as described in 10 Code of Federal Regulations (CFR) Parts 60, 71, and 72.	B.2.1
2.2.2.B.	B.Items and natural barriers important to waste isolation as described in 10 CFR Part 60.	B.2.2
2.2.2.C.	C.Items required for the control and management of site-generated radioactive waste other than spent fuel and high level waste.	B.2.3
2.2.2.D.	D.Items required for the protection of items important to safety and waste isolation from the hazards of fire.	B.2.4
2.2.2.E.	E.Items not intended to perform a safety function but whose failure could impair the capability of other items to perform their intended safety or waste isolation function.	B.2.5
2.2.2.F.	F.Items required for physical protection as defined by 10 CFR Part 73.	B.2.6
2.2.2.G.	G.Items required to control occupational radiological exposure.	B.2.7
2.2.3 2.2.3A.	2.2.3Controlling Activities The QA program shall apply to site characterization data and samples.	B.3 B.3.1
2.2.3A. Note:	NOTE:Site characterization for the purpose of QA program applicability includes activities related to sample collection and the collection and analysis of data to support performance confirmation or performance assessments.	
2.2.3B.	B.The QA program shall apply to activities related to the items on a Q-List (such as design, procurement, construction, fabrication, production, handling, packaging, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, and decontamination).	B.3.2
2.2.3C.	C.The QA program shall apply to those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.	B.3.3
2.2.3D.	D.The QA program shall apply to activities related to the high-level waste form development through qualification, production, and acceptance.	B.3.4
2.2.3E.	E.The QA program shall apply to activities associated with characterization of DOE spent nuclear fuel, and conditioning through acceptance of DOE spent nuclear fuel.	B.3.5

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2.2.4A.	Applying Quality Assurance Controls QA controls (grading) shall be applied to the degree commensurate with the: A.Function or end use of the item.	B.4 B.4.1
2.2.4B.	B.Consequence of failure (risk) of the item.	B.4.2
2.2.4C.	C.Importance of the data being collected or analyzed.	B.4.3
2.2.4D.	D.Complexity of design or fabrication of the item or design or implementation of the activity.	B.4.4
2.2.4E.	E.Reliability of the process.	B.4.5
2.2.4F.	F.Reproducibility of the results.	B.4.6
2.2.4G.	G.Uniqueness of the time or degree of standardization.	B.4.7
2.2.4H.	H.History of the item or service quality.	B.4.8
2.2.4I.	I.Necessity for special controls or processes.	B.4.9
2.2.4J.	J.Degree to which functional compliance can be demonstrated through inspection or test.	B.4.10
2.2.5 2.2.5.:1s	Planning Work Planning shall be documented to ensure work is accomplished under suitably controlled conditions.	B.5
2.2.5A.	Planning elements shall include, as appropriate: A.Definition of the work scope, objectives, and a listing of the primary tasks involved.	B.5.1
2.2.5B.	B.Identification of scientific approach or technical methods used to collect, analyze, or study results of applicable work.	B.5.2
2.2.5C.	C.Identification of applicable standards and criteria.	B.5.3
2.2.5D.	D.Identification and selective application, or development, of appropriate implementing documents.	B.5.4
2.2.5E.	E.Identification of field and laboratory testing equipment, or other equipment.	B.5.5
2.2.5F.	F.Identification of, or provisions for the identification of required records, and the recording of objective evidence of the results of the work performed.	B.5.6
2.2.5G.	G.Identification of QA program verifications of the work performed.	B.5.7
2.2.5H.	H.Identification of prerequisites, special controls, environmental conditions, processes, or skills.	B.5.8
2.2.5I.	I.Identification of computer software.	B.5.9
2.2.6 2.2.6.:1s	Surveillances Surveillances shall be conducted to evaluate the quality of selected work subject to the QARD.	B.6
2.2.6A.	Surveillances shall be: A.Conducted to verify the quality of work in progress; to identify conditions adverse to quality; to ensure that prompt corrective action is taken by management responsible for performing the work; and to verify the timely implementation, adequacy, and effectiveness of corrective action.	B.6.1

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2.2.6B.	B.Performed by personnel who are knowledgeable about, and not directly responsible for, the work under surveillance.	B.6.2
2.2.6C.	C.Documented in a report to appropriate management.	B.6.3
2.2.7.:1s	Management Assessments The Office of Civilian Radioactive Waste management shall perform or direct the performance of management assessments of Affected Organizations by personnel outside the QA organization.	B.7
2.2.7A.	Management Assessment shall: A.Be planned and documented, and performed annually.	B.7.1
2.2.7B. 2.2.7B.1.	B.Evaluate the: 1.Adequacy of resources and personnel provided to achieve and assure quality	B.7.2.
2.2.7B.2.	2.Adequacy of the QA program	B.7.2.2
2.2.7B.3.	3.Effectiveness of the QA program	B.7.2.3
2.2.7C.	C.Be documented and results shall be distributed to affected organization management.	B.7.3
2.2.8 2.2.8.:1s	Readiness Reviews The need for readiness reviews shall be identified by Affected Organization management for major scheduled or planned work to ensure program objectives are met.	B.8
2.2.8.:1s 2.2.8A.	Where needed, readiness review shall be conducted for the planned scope of work to ensure that objective evidence exists demonstrating that: A.Work prerequisites have been satisfied.	B.8.1
2.2.8B.	B.Personnel have been suitably trained and qualified.	B.8.2
2.2.8C.	C.Detailed implementing documents and management controls are available and approved.	B.8.3
2.2.9 2.2.9A.	Peer Reviews A.Peer reviews shall be conducted when the adequacy of information or the suitability of implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices.	B.9 B.9.1
   2.2.9A.1.	The following conditions are situations for which a peer review shall be considered: Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.	B.9.1.1
2.2.9A.2.	Decisions or interpretations having significant impact on performance assessment results will be made.	B.9.1.2
2.2.9A.3.	Novel or beyond the state-of-the-art testing, plans and procedures, or analyses will be utilized.	B.9.1.3
2.2.9A.4.	Detailed technical criteria or standard industry procedure are not available.	B.9.1.4
2.2.9A.5.	Results or tests are not reproducible or repeatable.	B.9.1.5
2.2.9A.6.	6.Data or interpretations are ambiguous.	B.9.1.6

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2.2.9A.7.	7.Data adequacy is questionable (e.g., the data may not have been collected in conformance with an established QA program).	B.9.1.7
2.2.9B.	B.Management shall determine the need for and, as appropriate, shall initiate peer reviews when the adequacy of a critical body of information can be established by alternate means, but there is significant disagreement regarding the applicability or appropriateness of the alternate means.	B.9.2
2.2.9C. 2.2.9C.1.	C.In conducting a peer review, management shall ensure that the: 1.Number of the peer reviewers is commensurate with the complexity of work to be reviewed, its importance to Program objectives, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning issues under review.	B.9.3 B.9.3.1
2.2.9C.2.	2.Collective technical expertise and qualifications of the peer reviewers span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought.	B.9.3.2
2.2.9C.3.	3.Technical areas central to the work to be reviewed receive appropriate proportional representation among the peer reviewers.	B.9.3.3
2.2.9C.4.	4.Potential for technical or organizational partiality is minimized.	B.9.3.4
2.2.9C.5.	5.Peer review group chairperson is identified.	B.9.3.5
2.2.9D. 2.2.9D.1.	Peer reviews shall be performed by individuals that have: 1.Technical qualifications in the review area at least equivalent to that needed for the work under review.	B.9.4 B.9.4.1
2.2.9D.2.	2.Technical credentials that are recognized and verifiable.	B.9.4.2
2.2.9D.3.:1s thru 2s	Independence from the work under review. Independence means that the individual was not involved as a participant, supervisor, technical reviewer or advisor in the work under review and is, to the extent practical, free from any funding considerations.	B.9.4.3
2.2.9D.3. Note:	Note:In those cases where total independence cannot be met, the rationale as to why someone of equivalent technical qualification and greater independence was not selected shall be documented in the peer review report.	
2.2.9E. 2.2.9E.1.	E.Initiation of the peer review shall require the development of a planning document that: Specifies the work to be reviewed.	B.9.5 B.9.5.1
2.2.9E.2.	Identifies the size and spectrum of the peer review group.	B.9.5.2
2.2.9E.3.	Describes the expected method and reporting schedule.	B.9.5.3
2.2.9E.4. 2.2.9E.4.a.	Establishes review criteria that shall include, as appropriate: Validity of the assumptions.	B.9.5.4 B.9.5.4.1
2.2.9E.4.b.	Alternate interpretations.	B.9.5.4.2
2.2.9E.4.c.	Adequacy of requirements and criteria.	B.9.5.4.3
2.2.9E.4.d.	Appropriateness and limitations of the methods and implementing documents used to complete the work under review.	B.9.5.4.4
2.2.9E.4.e.	Adequacy of application.	B.9.5.4.5
2.2.9E.4.f.	Accuracy of calculations.	B.9.5.4.6

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2.2.9E.4.g.	Validity of conclusions.	B.9.5.4.7
2.2.9E.4.h.	h.Uncertainty of results and impact if wrong.	B.9.5.4.8
2.2.9F.1.	F.The peer review chairperson shall provide a report that: 1.Is signed by each peer reviewer or contains information detailing which peer reviewers have chosen not to sign and why.	B.9.6 B.9.6.1
2.2.9F.2.	2.States the work or issue that was reviewed and the conclusions of the review.	B.9.6.2
2.2.9F.3.	3.Includes individual statements by the peer reviewers reflecting dissenting views or additional comments, as appropriate.	B.9.6.3
2.2.9F.4.	4.Includes a listing of the peer reviewers and a statement that the qualifications and experience of each reviewer have been evaluated and are acceptable.	B.9.6.4
2.2.10	Document Review Implementing documents and documents that specify technical or quality requirements shall be reviewed to the following requirements and for any additional requirements specified by the applicable section of the QARD.	B.10
2.2.10A.:1s	A.Review criteria shall be established before performing the review.	B.10.1
2.2.10A.:2s	The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements.	B.10.2
2.2.10B.	B.Pertinent background information or data shall be made available to the reviewers by the organization requesting the review if the information is not readily available to the reviewer.	B.10.3
2.2.10C.	C.The review shall be performed by individuals other than the preparer.	B.10.4
2.2.10D.	D.Reviewers shall be technically competent for the subject area of the document being reviewed.	B.10.5
2.2.10E.	E.The scope of the review shall consider all aspects of the document.	B.10.6
2.2.10E.1.:1s	1.Each organization or technical discipline affected by the document shall review the document according to the established review criteria.	B.10.6.1
2.2.10E.1.:2s	Changes to the document shall be reviewed by those organizations or technical disciplines affected by the change.	B.10.6.2
2.2.10E.2.:1s	2.The QA organization shall review implementing documents and changes thereto that translate the QARD into work processes as described in Subsection 2.2.1, Quality Assurance Program Documents.	B.10.6.3
2.2.10E.2.:2s	The QA organization also shall review changes to other documents if they were required to review the previous version, unless the QA organization has concurred that its review is no longer required.	B.10.6.4
2.2.10F.	F.Mandatory comments resulting from the review shall be documented and resolved before approving the document.	B.10.7
2.2.11.:1s	Quality Assurance Program Information Management Affected Organization management shall on a continuing basis be appraised of the status, adequacy and compliance aspects of the QA Program.	B.11 B.11.1
2.2.11.:2s	Appropriate management shall receive, as a minimum, audit reports, surveillance reports, trend reports, and management assessment reports.	B.11.2

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2.2.12 2.2.12A.	Personnel Qualification A.Each Affected Organization shall indoctrinate and train personnel as follows.	B.12 B.12.1
2.2.12A.1.	1.Determine required indoctrination and training.	B.12.1.1
2.2.12A.2.	2.Ensure personnel are indoctrinated and trained, as needed, to achieve initial proficiency; maintain proficiency; and to adapt to changes in technology, methods or job responsibilitities.	B.12.1.2
2.2.12A.3.	3.Evaluate and assess the need for additional indoctrination and training as assignments, positions, or implementing documents change.	B.12.1.3
2.2.12A.4.	4.Ensure indoctrination and training are completed prior to performing the work.	B.12.1.4
2.2.12A.5.	5.Ensure that peronnel are indoctrinated in the following topics as they relate to a particular function:	B.12.1.5
2.2.12A.5.a.	a.General criteria, including the QARD, applicable codes, regulations, and standards.	B.12.1.5.1
2.2.12A.5.b.	b.Applicable implementing documents.	B.12.1.5.2
2.2.12A.5.c..	c.Job responsibilities and authority.	B.12.1.5.3
2.2.12B.	B.For personnel who perform or manage design, scientific investigation, software development activities and for personnel who verify or manage the verification of design, scientific investigation, software development activities, or items, Affected organizations shall ensure that:	B.12.2
2.2.12B.1.	1.Descriptions are established for the positions those personnel occupy.	B.12.2.1
2.2.12B.2.	2.Minimum education and experience requirements are established for each position commensurate with the scope, complexity, and nature of the work or documented justification is provided for positions for which no specific minimum education and experience is required.	B.12.2.2
2.2.12B.3.	3.Personnel have experience and education commensurate with the minimum requirements established.	B.12.2.3
2.2.12B.4.	4.Minimum education and experience are verified or, when minimum education and experience cannot be verified, documented justification is provided for the personnel assignment.	B.12.2.4
2.2.13	Testing, and Auditing Personnel who perform inspection, nondestructive examination, testing, and auditing shall be qualified in accordance with the requirements of the applicable QARD section covering the activity and QARD Subsection 2.2.12, Personnel Qualification..	B.13
Section 3	DESIGN CONTROL	C
3.2 3.2.1	3.2REQUIREMENTS Design Input Control Applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) shall be controlled by those responsible for the design according to the following requirements:	C.1

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3.2.1A	A.Design inputs shall be identified and documented, and their selection reviewed and approved by those responsible for the design.	C.1.1
3.2.1B	B.Design inputs shall be specified and approved on a timely basis and to the level of detail necessary to permit the design work to be carried out in a correct manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.	C.1.2
3.2.1C	C.Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.	C.1.3
3.2.1D	D.Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds.	C.1.4
3.2.2 3.2.2A.	3.2.2Design Process The design process shall be controlled according to the following requirements: A.Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner.	C.2 C.2.1
3.2.2B.	B.Design documents shall be adequate to support design, fabrication, construction, and operation.	C.2.2
3.2.2C.	C.Appropriate standards shall be identified and documented, and their selection reviewed and approved.	C.2.3
3.2.2D.	D.Changes from specified standards, including the reasons for the change, shall be identified, approved, documented, and controlled.	C.2.4
3.2.2E.	E.Design methods, materials, parts, equipment, and processes that are essential to the function of an item shall be selected and reviewed for suitability of application.	C.2.5
3.2.2F.	F.Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.	C.2.6
3.2.2G.	G.Design documents shall be sufficiently detailed as to purpose, methods, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the documents and verify their adequacy without recourse to the originator.	C.2.7
3.2.2H.:1s	H.The final design shall identify assemblies or components that are part of the item being designed.	C.2.8
3.2.2H.:2s	If a commercial grade assembly or component is modified or selected by special inspection or testing to meet requirements that are more restrictive than the supplier's published product description, then the assembly or component shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference.	C.2.8.1
3.2.2I.	I.Drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.	C.2.9
3.2.3 3.2.3A.	3.2.3Design Analyses A.Design analyses shall be planned, controlled, and documented.	C.3 C.3.1
3.2.3B.	B.Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval.	C.3.2

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3.2.3C.	C.Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable.	C.3.3
3.2.3D.	D.Computer software used to perform design analyses shall be developed or qualified, and used according to the requirements of Supplement I, Software.	C.3.4
3.2.3E. 3.2.3E.1.	Documentation of design analyses shall include: 1.Definition of the objective of the analyses.	C.3.5 C.3.5.1
3.2.3E.2.	2.Definition of design inputs and their sources.	C.3.5.2
3.2.3E.3.	3.Results of literature searches or other applicable background data.	C.3.5.3
3.2.3E.4.	4.Identification of assumptions.	C.3.5.4
3.2.3E.5.	5.Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem.	C.3.5.5
3.2.3E.6.	6.Identification of the originator, reviewer, and approver.	C.3.5.6
3.2.4	3.2.4Design Verification In addition to reviewing completed design analyses and design output in accordance with QARD Subsection 2.2.10, Document Review, the following design control requirements shall be applied:	C.4
3.2.4A. 3.2.4A.1	Design verification shall be performed to determine the adequacy of design by using one or a combination of the following methods: 1.Design review.	C.4.1 C.4.1.1
3.2.4A.2.	2.Alternate calculations.	C.4.1.2
3.2.4A.3.	3.Qualification testing.	C.4.1.3
3.2.4B.	B.The particular design verification methods shall be identified and its use justified.	C.4.2
3.2.4C.	C.The results of design verification shall be documented, including the identification of the verifier.	C.4.3
3.2.4D.:1s	D.Design verification shall be performed by competent individuals or groups other than those who performed the original design but may be from the same organization.	C.4.4
3.2.4D.:2s 3.2.4D.1.	If necessary, this verification may be performed by the originator's supervisor provided: 1.The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or	 C.4.4.1
3.2.4D.2.	2.The supervisor is the only individual in the organization competent to perform the verification.	C.4.4.2
3.2.4D.3.	3.The verification is not hastily and superficially done.	C.4.4.3
3.2.4D.4.	4.The determination to use the supervisor is documented and approved, in advance, with concurrence of the QA organization.	C.4.4.4
3.2.4E.	E.Design verification shall be performed at appropriate times during the design process.	C.4.5

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3.2.4E.1.:1s	1.Verification shall be performed before release for procurement, manufacture, or construction or release to another organization for use in other design work.	C.4.5.1.1
3.2.4E.1.:2s	In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to support schedule requirements.	C.4.5.1.2
3.2.4E.1.:3s	Unverified portions of the design shall be clearly identified and controlled.	C.4.5.1.3
3.2.4E.2.	2.In all cases, design verification shall be completed before relying on the item to perform its function.	C.4.5.2
3.2.4F.	F.The extent of the design verification required shall be a function of the importance to safety or waste isolation, complexity of design, degree of standardization, state of the art, and similarity with previously proven designs.	C.4.6
3.2.4G.	G.Where the design has been subjected to a verification process in accordance with this Quality Assurance Requirements and Description, the verification process need not be duplicated for identical designs.	C.4.7
3.2.4H. 3.2.4H.1.	Use of previously proven designs shall be controlled according to the following requirements: 1.The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.	C.4.8 C.4.8.1
3.2.4H.2.	2.Known problems affecting standard or previously proven designs and their effects on other features shall be considered.	C.4.8.2
3.2.4H.3.	3.The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.	C.4.8.3
3.2.4I.:1s	I.Changes in previously verified designs shall require reverification.	C.4.9.1
3.2.4I.:2s	Such verification shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analysis upon which the design is based.	C.4.9.2
3.2.5 3.2.5A.	3.2.5Design Reviews Design reviews shall be controlled and performed to ensure: A.The design inputs were correctly selected and incorporated.	C.5 C.5.1
3.2.5B.	B.Assumptions necessary to perform the design were adequately described, reasonable and where applicable, identified as requiring confirmation as the design proceeds.	C.5.2
3.2.5C.	C.Appropriate design methods, and computer programs when applicable, were used.	C.5.3
3.2.5D.	D.The design outputs are reasonable compared to design inputs.	C.5.4
3.2.5E.	E.The necessary design input for interfacing organizations were specified in the design documents.	C.5.5
3.2.6	3.2.6Alternate Calculations The appropriateness of assumptions, input data, and the computer program or other calculation method used shall be reviewed, and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses.	C.6
3.2.7 3.2.7A.	3.2.7Qualification Testing A.If design adequacy is to be verified by qualification tests, the tests shall be in accordance with Section 11.), Test Control.	C.7 C.7.1
3.2.7B.	B.The test configuration shall be defined and documented.	C.7.2

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3.2.7C.:1s	C.Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions.	C.7.3.1
3.2.7C.:2s	Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.	C.7.3.2
3.2.7D.	D.If the tests verify only specific design features, then the other features of the design shall be verified by other means.	C.7.4
3.2.7E.	E.Test results shall be documented and evaluated to ensure that test requirements have been met.	C.7.5
3.2.7F.	F.if qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and item modified and retested or otherwise verified to ensure satisfactory performance.	C.7.6
3.2.7G.	G.When tests are being performed on models or mockups, scaling laws shall be established and reviewed and approved.	C.7.7
3.2.7H.	H.The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.	C.7.8
3.2.8 3.2.8A.	3.2.8Design change Control Design changes shall be controlled according to the following requirements: A.Changes to final designs, field changes, and nonconforming items dispositioned "use-as-is" or "repair" shall be justified and shall be subject to design control measures commensurate with those applied to the original design.	C.8 C.8.1
3.2.8B.	B.Design control measures for changes shall include provisions to assess the effect of the changes on the overall previously verified design and ensure that the design analyses for the item are still valid.	C.8.2
3.2.8C. 3.2.8C.1.	C. Changes shall be approved by the same affected groups or ganizations that approved the original design documents: 1.If an organization that originally was responsible for approving a particular deign document is no longer responsible, then a new responsible organization shall be designated; and	C.8.3 C.8.3.1
3.2.8C.2.	2.The designated approving organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.	C.8.3.2
3.2.8D.:1s	D.The design process and design verification methods and implementing documents shall be reviewed and modified, as necessary, when a significant design change is necessary because of an incorrect design.	C.8.4.1
3.2.8D.:2s	These design deficiencies shall be documented in accordance with Section 16.0, Corrective Action.	C.8.4.2
3.2.8D.:3s	Additionally, if the incorrect design causes constructed or partially constructed systems, structures, or components to be nonconforming, the affected items shall be controlled in accordance with Section 15.0, Nonconformances.	C.8.4.3
3.2.8E.	E.Field changes shall be incorporated into affected design documents when such incorporation is appropriate, and when a field change is approved other than by revision to the affected design documents.	C.8.5
3.2.8F.	F.Design changes that impact related implementing documents or training programs shall be communicated to organizations affected by the change.	C.8.6

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3.2.9 3.2.9A.	3.2.9Design Interface Control A.Design interfaces shall be identified and controlled.	C.9 C.9.1
3.2.9B.	B.Design efforts shall be coordinated among participating organizations and groups.	C.9.2
3.2.9C.	C.Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating deign organizations and groups for the review, approval, release, distribution, and revision of documents involving design interfaces.	C.9.3
3.2.9D.	D.Design information transmitted across interfaces shall be documented and controlled.	C.9.4
3.2.9E.	E.The status of the design information or document provided shall be identified in transmittals. Designs or portions of designs that require further development, analysis, review, or approval shall be identified.	C.9.5
3.2.9F.	F.When it is necessary to initially transmit design information orally or by other informal means, the design information shall be promptly confirmed with formal documentation initiated in accordance with the initiating organizations approved implementing document.	C.9.6
Section 4 PROCUR		D
4.2 4.2.1	4.2REQUIREMENTS 4.2.1Procurement Document Preparation Procurement documents issued by each Affected Organization shall include the following provisions, as applicable, to the items or service being procured:	 D.1
4.2.1.A.	A.A statement of the scope of work to be performed by the supplier.	D.1.1
4.2.1.B.	B.Technical requirements including:	D.1.2
4.2.1B.1.	1.Design bases shall be identified or referenced.	D.1.2.1
4.2.1B.2.:1s	2.Specific documents (such as drawings, codes, standards, regulations, procedures, or instructions) that describe the technical requirements of the items or services to be furnished shall be specified.	D.1.2.2.1
4.2.1B.2.:2s	The revision level or change status of these documents shall also be identified.	D.1.2.2.2
4.2.1B.3.	3.Tests, inspections, or acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.	D.1.2.3
4.2.1C.I.:1s	C.Quality Assurance Program Requirements including: 1.A requirement for the supplier to have a documented Quality Assurance (QA) program that implements applicable Quality Assurance Requirements and Description (QARD) requirements prior to the initiation of work.	D.1.3 D.1.3.1.1
4.2.1C.1.:2s	The extent of the QA program shall depend on the scope, nature, or complexity of the item or service being procured.	D.1.3.1.2
4.2.1C.2.	2.A requirement for the supplier to incorporate the appropriate QARD requirements into any subtier supplier-issued procurement document.	D.1.3.2
4.2.1C.3.:1s	3.When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's or another Affected Organization's QA program provided the work is adequately addressed.	D.1.3.3.1
4.2.1C.3.:2s	In these cases, procurement documents shall specify that the purchaser's or another Affected Organization's implementing documents are applicable to the supplier and that the purchaser shall provide these applicable documents to them	D.1.3.3.2

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4.2.1D.	D.Right of access to supplier facilities and records for inspection of audit by the purchaser, OCRWM, or other designee authorized by the purchaser.	D.1.4
4.2.1E.	E.Provisions for establishing hold points beyond which work cannot proceed without purchaser authorization.	D.1.5
4.2.1F.	F.Documentation required to be submitted to the purchaser for information, review, or acceptance:	D.1.6
4.2.1F.1.	1.The document submittal schedule shall be identified.	D.1.6.1
4.2.1F.2.	2.If the purchaser requires the supplier to maintain documentation that will become QA records, the retention times and disposition requirements shall be identified.	D.1.6.2
4.2.1G.	G.Purchaser requirements for the supplier to report nonconformance and the purchaser approval of the disposition of nonconformance.	D.1.7
4.2.1H.	H.Identification of any spare and replacement parts or assemblies and the appropriate technical and QA data required for ordering.	D.1.8
4.2.2 4.2.2A.	4.2.2Procurement Document Review and Approval A.Procurement document reviews in accordance with Subsection 2.2.10, Document Review, shall be performed and documented prior to issuance of the procurement documents to the supplier.	D.2 D.2.1
4.2.2B.	B.A review of the procurement documents and any changes thereto shall be made to verify that documents include appropriate provisions to ensure that items or services will meet the governing requirements.	D.2.2
4.2.2C.	C.Reviews shall ensure that all applicable technical and QA program requirements are included.	D.2.3
4.2.2D.	D.Reviews shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and scope of the procurement.	D.2.4
4.2.2E.	E.Procurement document reviewers shall include representatives from the technical and QA organizations.	D.2.5
4.2.2F.	F.Procurement documents shall be approved.	D.2.6
4.2.3 4.2.3A.	4.2.3Procurement Document Change A.Changes to the scope of work, technical requirements, QA program requirements, right of access, documentation requirements, nonconformance, hold points, and lists of spare and replacement parts delineated in procurement documents shall be subject to the same degree of control as used in the preparation of the original documents.	D.3 D.3.1
4.2.3B.:1s	B.Changes made as a result of proposal/bid evaluations or precontract negotiations shall be incorporated into the procurement documents.	D.3.2.1
4.2.3B.:2s	The evaluation of these changes and the resulting impact shall be completed before the contract is awarded.	D.3.2.2
4.2.3B.I.	This evaluation shall consider: 1.Appropriate requirements as specified in this Sec.	D.3.2.2.1
4.2.3B.2.	2.Additional or modified design criteria.	D.3.2.2.2
4.2.3B.3.	3.Analysis of exceptions or changes requested or specified by the supplier and a determination of the impact such changes have on the intent of the procurement documents or quality of the items or service to be furnished.	D.3.2.2.3
Section 5 IMPLEMENTING DOCUMENT		E

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5.2	Section 5.2REQUIREMENTS Work shall be performed in accordance with controlled implementing documents.	E.1
5.2.1:1s	5.2.1Types of Implementing Documents The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed.	E.2 E.2.1
5.2.1:2s	Implementing documents include documents such as procedures, instructions, and drawings, with the exception of drawings governed by Section 3.0, Design Control.	E.2.2
5.2.2	5.2.2Content of Implementing Documents Implementing documents shall include the following information as appropriate to the work to be performed:	E.3
5.2.2A.	A.Responsibilities and organizational interfaces of the organizations affected by the document.	E.3.1
5.2.2B.	B.Technical and regulatory requirements.	E.3.2
5.2.2C.:1s	C.A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations.	E.3.3.1
5.2.2C.:2s	The organization responsible for preparing the document shall determine the appropriate level of detail.	E.3.3.2
5.2.2D.	D.Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished.	E.3.4
5.2.2E.	E.Prerequisites, limits, precautions, process parameters, and environmental conditions.	E.3.5
5.2.2F.	F.Quality verification points and hold points.	E.3.6
5.2.2G.	G.Methods for demonstrating that the work was performed as required (such as provisions for recording inspection and test results, checkoff lists, or signoff blocks).	E.3.7
5.2.2H.	H.Identification of the lifetime and nonpermanent QA records generated by the implementing document.	E.3.8
5.2.2I.	I.Identification of associated items and activities.	E.3.9
5.2.3	5.2.3Review and Approval of Implementing Documents Implementing documents shall be reviewed, approved, and controlled in accordance with Section 6.0, Document Control.	E.4
5.2.4	5.2.4Compliance with Implementing Documents Individuals shall comply with implementing documents, however:	E.5
5.2.4A.	A.When work cannot be accomplished as described in the implementing document, or accomplishment of such work would result in an undesirable situation, the work shall be stopped.	E.5.1
5.2.4B.	B.Work shall not resume until the implementing document is changed (in accordance with Section 6.0, Document Control) to reflect the correct work practices.	E.5.2
Section 6 DOCUMENT CONTROL		F
6.2 6.2.1	REQUIREMENTS 6.2.1Types of Documents Implementing documents and documents that specify technical requirements or quality requirements shall be controlled in accordance with this Sec.	 F.1
6.2.2	6.2.2Preparing Documents The responsibility for preparing and maintaining documents shall be assigned to the appropriate organization.	F.2
6.2.3	6.2.3Reviewing Documents Documents shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review.	F.3
6.2.4	6.2.4Approving Documents The organizational position responsible for approving the document for release shall be identified.	F.4
6.2.5	6.2.5Distribution and Use of Documents The distribution and use of documents, including changes and editorial corrections to documents, shall include the following:	F.5
6.2.5A.	A.Documents, either in hard copy or electronic media, used to perform work shall be distributed to, or made available to, and used at, the work location.	F.5.1
6.2.5B.	B.Effective dates shall be established for approved implementing documents.	F.5.2
6.2.5C.	C.The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work.	F.5.3
6.2.5D.	D.A method shall be established to identify the current status of each document that is required to be controlled in accordance with this Sec.	F.5.4
6.2.6A.	6.2.6Changes to Documents A.Changes to documents shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review, prior to approval for release.	F.6 F.6.1
6.2.6B.	B.Changes shall be approved for release by the designated organizational position that is responsible for the document.	F.6.2
6.2.6C.:1s	C.Implementing documents shall define the method used to incorporate changes.	F.6.3.1
6.2.6C.:2s	If the defined method is other than reissue of the entire controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.	F.6.3.2
6.2.6D.:1s	D.Implementing documents shall require that a history of changes to QA Program documents, including the reasons for the changes, be documented and maintained.	F.6.4.1
6.2.6D.:2s	This document history shall be reviewed each time additional changes to the document are proposed.	F.6.4.2
6.2.7	6.2.7Expedited Changes If an activity cannot be performed as listed in a document, and the change process would cause unreasonable delays, then an expedited change may be made at the work location by responsible management.	F.7
6.2.7A.:1s	A.After the expedited change has been authorized, the changes shall be processed through normal change process.	F.7.1.1
6.2.7A.:2s	This processing shall occur in a timely manner consistent with the type and nature of the document being changed.	F.7.1.2
6.2.7B.	B.Implementing documents shall describe the process to control expedited changes according to the following requirements.	F.7.2
6.2.7B.1.	1.The level of management with the authority to make expedited changes shall be identified.	F.7.2.1

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6.2.7B.2.	2.The time limits for processing expedited changes through the normal change process shall be specified.	F.7.2.2
6.2.7B.3.	3.An evaluation of the work shall be performed if the normal review process results in a change that is different from the expedited change.	F.7.2.3
6.2.8	6.2.8 Editorial corrections may be made to documents without being subject to review requirements, but such corrections shall be distributed as a revision or change to the document.	F.8
6.2.8A. 6.2.8A.1.	A.The following items are considered editorial corrections: 1.Correcting grammar or spelling.	F.8.1 F.8.1.1
6.2.8A.2.	2.Renumbering sections or Att.s which do not affect the chronological sequence of work	F.8.1.2
6.2.8A.3.	3.Changing the title or number of the document.	F.8.1.3
6.2.8A.4.	4.Updating organizational titles.	F.8.1.4
6.2.8A.4. :Note	Note:A change in an organizational title accompanied by a change in responsibilities is not considered an editorial correction.	
6.2.8B.	B.The organizational position responsible for approving the document for release shall approve editorial corrections.	F.8.2
Section 7	CONTROL OF PURCHASED ITEMS AND SERVICES	G
7.2 7.2.1	7.2REQUIREMENTS Procurement Planning Procurements shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall:	G.1
7.2.1A.	A.Identify procurement methods and organizational responsibilities.	G.1.1
7.2.1B.	B.Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.	G.1.2
7.2.1C.	C.Identify and document the sequence of actions and milestones needed to effectively complete the procurement.	G.1.3
7.2.1D.1.	D.Provide for the integration of the following activities: 1.Procurement document preparation, review, and change control according to the requirements of Section 4.0, Procurement Document Control.	G.1.4.1
7.2.1D.2.	2.Selection of procurement sources.	G.1.4.2
7.2.1D.3.	3.Proposal/bid evaluation and award.	G.1.4.3
7.2.1D.4.	4.Evaluation of supplier performance.	G.1.4.4
7.2.1D.5.	5.Verifications including any hold and witness point notifications.	G.1.4.5
7.2.1D.6.	6.Control of nonconformance.	G.1.4.6
7.2.1D.7.	7.Corrective action.	G.1.4.7
7.2.1D.8.	8.Acceptance of the item or service.	G.1.4.8
7.2.1D.9.	9.Identification of QA records.	G.1.4.9
7.2.1E.	E.Be accomplished as early as possible, and no later than at the start of those procurement activities which are required to be controlled.	G.1.5
7.2.1F.	F.Be performed relative to the level of importance, complexity, and quantity of the items or service being procured and the supplier's quality performance.	G.1.6
7.2.1G.	G.Include the involvement of the QA organization.	G.1.7

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7.2.2 7.2.2A.	7.2.2Source Evaluation and Selection A.Supplier selection shall be based on an evaluation, performed before the contract is awarded, of the supplier's capability to provide items or services in accordance with procurement document requirements.	G.2 G.2.1
7.2.2B.:1s	B.The organizational responsibilities for source evaluation and selection shall be identified, including provisions for input from the QA organization.	G.2.2.1
7.2.2B.:2s	If a source evaluation board for a procurement is initiated by OCRWM, OQA shall have a voting member.	G.2.2.2
7.2.2C.1.	C.Measures for evaluating and selecting procurement sources shall include one or more of the following elements: 1.Evaluation of the supplier's history for providing an identical or similar product which performs satisfactorily in actual use.	G.2.3 G.2.3.1
7.2.2C.2.	2.Evaluation of the supplier's current QA records supported by any documented qualitative and quantitative information.	G.2.3.2
7.2.2C.3.	3.Evaluation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel, and QA program implementation.	G.2.3.3
7.2.2D.	D.The results of procurement source evaluation and selection shall be documented.	G.2.4
7.2.3 7.2.3A.:1s	Proposal/Bid Evaluation A.The proposal/bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements.	G.3 G.3.1.1
7.2.3A.:2s	This evaluation shall be performed by designated, technically qualified organizations including the QA organization.	G.3.1.2
7.2.3B. 7.2.3B.1.	B.The evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured: 1.Technical considerations.	G.3.2 G.3.2.1
7.2.3B.2.	2.QA program requirements.	G.3.2.2
7.2.3B.3.	3.Supplier personnel.	G.3.2.3
7.2.3B.4.	4.Supplier production capability.	G.3.2.4
7.2.3B.5.	5.Supplier past performance.	G.3.2.5
7.2.3B.6.	6.Alternatives.	G.3.2.6
7.2.3B.7.	7.Exceptions.	G.3.2.7
7.2.3C.	C.Before the contract is awarded the purchaser shall resolve, or obtain commitment to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.	G.3.3
7.2.3D.	D.Supplier QA programs shall be evaluated either before or after contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to the QARD.	G.3.4
7.2.3E.	E.Supplier QA programs shall be accepted by the purchaser before the supplier starts work subject to the QARD.	G.3.5
7.2.4 7.2.4A.	7.2.4Supplier Performance Evaluation A.The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier's performance.	G.4 G.4.1

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7.2.4A.1.	The measures shall include: 1.Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents.	G.4.1.1
7.2.4A.2.	2.Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.	G.4.1.2
7.2.4A.3.	3.Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements.	G.4.1.3
7.2.4A.4.	4.Identifying and processing necessary change information.	G.4.1.4
7.2.4A.5.	5.Establishing the method to be used to document information exchanges between purchaser and supplier.	G.4.1.5
7.2.4A.6.	6.Establishing the extent of source surveillance and inspection.	G.4.1.6
7.2.4B.	B.The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, and the supplier's quality performance.	G.4.2
7.2.4C.:1s	C.Verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement.	G.4.3.1
7.2.4C.:2s	Verifications shall include supplier audits used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's QA program.	G.4.3.2
7.2.5 7.2.5A.	Control of Supplier Generated Documents A.Supplier generated documents shall be controlled, processed, and accepted in accordance with the requirements established in the procurement documents.	G.5 G.5.1
7.2.5B.:1s	B.Measures shall be implemented to ensure that the submittal of these documents is accomplished in accordance with the procurement document requirements.	G.5.2.1
7.2.5B.:2s	These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data compared against the acceptance criteria.	G.5.2.2
7.2.6A.	7.2.6Acceptance of Items or Services A.The supplier shall verify that furnished items or services comply with the purchaser's procurement requirements before offering the items or services for acceptance.	G.6 G.6.1
7.2.6B.:1s	B.The supplier shall provide the purchaser objective evidence that items or services conform to procurement documents.	G.6.2.1
7.2.6B.:2s	The documentation shall be available at the purchaser's facility before the item is installed or before the service is accepted.	G.6.2.2
7.2.6C.	C.Methods for accepting supplier furnished items or services shall include one or more of the following, as appropriate to the items or services being procured:	G.6.3
7.2.6C.1.	1.Evaluating the supplier certificate of conformance.	G.6.3.1
7.2.6C.2.	2.Performing one or a combination of source verification, receiving inspection, or post-installation test.	G.6.3.2
7.2.6C.3.	3.Technical verification of the item or service.	G.6.3.3
7.2.6C.4.	4.Surveillance or audit of the work.	G.6.3.4
7.2.6C.5.	5.Review of objective evidence (such as certifications, stress reports, or personnel qualifications) for conformance to the procurement document requirements.	G.6.3.5
7.2.7A.	7.2.7Certificate of Conformance When a certificate of conformance is used to accept an item or service: A.The certificate shall identify the purchased item or service to the specific procurement document.	G.7 G.7.1
7.2.7B.:1s	B.The certificate shall identify the specific procurement document requirements met by the purchased item or service.	G.7.2.1
7.2.7B.:2s	The procurement document requirements identified shall include any approved changes, waivers, or deviations applicable to the item or service.	G.7.2.2
7.2.7C.	C.The certificate shall identify any procurement document requirements that have not been met together with an explanation and the means for resolving the nonconformance.	G.7.3
7.2.7D.	D.The certificate shall be signed or otherwise authenticated by a person who is responsible for this QA function and whose responsibilities and position are described in the supplier's QA program.	G.7.4
7.2.7E.	E.The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review and approval of the certificates, shall be described in the supplier's QA program.	G.7.5
7.2.7F.:1s	F.Measures shall be identified to verify the validity of supplier certificates and the effectiveness of the certification process (such as by audit of the supplier or by an independent inspection or test of the item).	G.7.6.1
7.2.7F.:2s	Verifications shall be conducted at intervals commensurate with the past quality performance of the supplier.	G.7.6.2
7.2.8 7.2.8.:1s 7.2.8.:2s	7.2.8 Source Verification The purchaser may accept an item or service by monitoring, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification.	G.8
7.2.8A.	A.Source verification shall be implemented consistent with the supplier's planned inspections, examinations, or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item.	G.8.1
7.2.8B.	B.Documented evidence of acceptance of source verified items or services shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.	G.8.2
7.2.8C.	C.Source verification shall be performed by personnel qualified in accordance with the Section 2.0, Quality Assurance Program.	G.8.3
7.2.9 7.2.9A.	Receiving Inspection When receiving inspection is used to accept an item: A.The inspection shall consider the results of source verifications and audits and the demonstrated quality performance of the supplier.	G.9 G.9.1
7.2.9B.	B.The inspection shall be performed in accordance with established inspection implementing documents.	G.9.2

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7.2.9C.	C.The inspection shall verify, as applicable, proper configuration, identification, dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.	G.9.3
7.2.9D.	D.The inspection shall be planned and executed according to the requirements of Section 10.0, Inspection.	G.9.4
7.2.9E.	E.Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation submittals.	G.9.5
7.2.10 7.2.10A.	Post-Installation Testing A.When post-installation testing is used as a method of acceptance, then post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier.	G.10 G.10.1
7.2.10B.	B.The test shall be in accordance with the requirements of Section 11.0, Test Control.	G.10.2
7.2.11	7.2.11 Control of Supplier Nonconformance The purchaser and supplier shall establish and document the process for disposition of items that do not meet procurement document requirements according to the following requirements.	G.11
7.2.11A.	A.The supplier shall evaluate nonconforming items according to the requirements of Section 15.0, Nonconformance	G.11.1
7.2.11B.:s1	B.The supplier shall submit a report of nonconformance to the purchaser including supplier recommended disposition (e.g., use-as-is or repair) and technical justification.	G.11.2.1
7.2.I1B.:s2 7.2.11B.1.	Reports of nonconformance related to procurement document requirements, or documents approved by the purchaser, shall be submitted to the purchaser for approval whenever one of the following conditions exist: 1.Technical or material requirements are violated.	G.11.2.2 G.11.2.2.1
7.2.11B.2.	2.A requirement in supplier documents, which have been approved by the purchaser, is violated.	G.11.2.2.2
7.2.11B.3.	3.The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.	G.11.2.2.3
7.2.11B.4.	4.The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.	G.11.2.2.4
7.2.11C.	C.The purchaser shall disposition the supplier's recommendation.	G.11.3
7.2.11D.	D.The purchaser shall verify implementation of the disposition.	G.11.4
7.2.12	7.2.12Commercial Grade Items Where design specifies the use of commercial grade items, the following requirements are an acceptable alternative to other requirements of this Sec.	G.12
7.2.12A.:1s	A.The commercial grade item shall be identified in an approved design output document.	G.12.1.1
7.2.12A.:2s	An alternate commercial grade item may be applied, provided the responsible design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and the application.	G.12.1.2

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7.2.12B.	B.Supplier evaluation and selection, when determined necessary by the purchaser based on the complexity and importance to safety, shall be in accordance with the requirements of the Subsection 7.2.2, Source Evaluation and Selection.	G.12.2
7.2.12C.	C.Commercial grade items shall be identified in the procurement document by the manufacturer's published product description.	G.12.3
7.2.12D.	D.After receipt of a commercial grade item, the purchaser shall ensure that:	G.12.4
7.2.12D.1.	1.Damage was not sustained during shipment.	G.12.4.1
7.2.12D.2.	2.The item received was the item ordered.	G.12.4.2
7.2.12D.3.	3.Inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements.	G.12.4.3
7.2.12D.4.	4.Documentation, as applicable to the item, was received and is acceptable.	G.12.4.4
Section 8	IDENTIFICATION AND CONTROL OF ITEMS	H
8.2 8.2.1 8.2.1.A	Requirements 8.2.1 Identification A. Identification shall be maintained on the items or in a manner which ensures that identification is established and maintained.	 H.1 H.1.1
8.2.1.B	B.Items shall be identified from the time of initial fabrication, or receipt, up to and including installation or end use.	H.1.2
8.2.1.C	C. Identification shall relate an item to an applicable design or other pertinent specifying document.	H.1.3
8.2.2 8.2.2.A	8.2.2 Physical Markings A. Item identification methods shall include use of physical markings if physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural control).	H.2 H.2.1
8.2.2.B 8.2.2.B.1	B. Physical markings, whene used, shall: 1. Be applied using materials and methods that provide a clear and legible identification.	H.2.2 H.2.2.1
8.2.2.B.2	2. Not detrimentally affect the function or service life of the item.	H.2.2.2
8.2.2.B.3	3. Be transferred to each part of an identified item when the item is subdivided.	H.2.2.3
8.2.2.B.4	Not be obliterated or hidden by surface treatments or coatings, or after installation unless other means of identification are substituted.	H.2.2.4
8.2.3 8.2.3.A	8.2.3 Traceability A.Item identification methods shall ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents.	H.3 H.3.1
8.2.3.B	B. Item traceability documentation shall ensure that the item can be traced at all times from its source through installation or end use.	H.3.2

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8.2.4 8.2.4.A	8.2.4 Conditional Requirements The controls for items shall address the following requirements, as applicable: A. If codes, or standards include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification or grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), then identification and traceability methods shall be specified in specifications.	H.4 H.4.1
8.2.4.B	B. If codes or standards do not include specific identification or traceability requirements, specifications shall specify identification and traceability methods appropriate to the item.	H.4.2
8.2.4.C	C. If items have a limited operating or shelf life specified, then methods shall be established that preclude using the item beyond the shelf or operating life.	H.4.3
8.2.4.D	D. If item storage is required, then methods shall be established for the control of item identification that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:	H.4.4
8.2.4.D.1	1.Maintenance or replacement of markings and identification tags damaged during handling or aging.	H.4.4.1
8.2.4.D.2	2. Protection of identification markings subject to excessive deterioration resulting from environmental exposure.	H.4.4.2
8.2.4.D.3	3. Updating related documentation.	H.4.4.3
Section 9	CONTROL OF SPECIAL PROCESSES	I
9.0 9.2.1.A	Requirements 9.2.1 Special Processes A. Special processes that control or verify quality shall be controlled according to the requirements of this section whether or not they are covered by existing codes and standards, or whether or not the quality requirements specified for an item exceed those of existing codes or standards.	 I.1 I.1.1
9.2.1.B 9.2.1.B.1	B. Processes to be controlled as special processes shall meet the following criteria: 1. The results are highly dependent on the control of the process; or	I.1.2 I.1.2.1
9.2.1.B.2	2. The results are highly dependent on the skill of the operator; and	I.1.2.2
9.2.1.B.3	3. Quality of the results cannot be readily determined by inspection or test of the item.	I.1.2.3
9.2.1.C	C. Based on this criteria, a list of the special processes that each Affected Organization will perform, or be responsible for performing, shall be established and maintained.	I.1.3
9.2.2	9.2.2 Personnel, Implementing Documents, and Equipment Qualifications Implementing documents shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Special process implementing documents shall include or reference	I.2
9.2.2.A	A.Qualification requirements for personnel, implementing documents, and equipment	I.2.1

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9.2.2.B	B.Conditions necessary for accomplishment of the special process. These conditions shall include proper equipment, controlled parameters of the process, calibration requirements, and traceability between the item or product, and individual performing the special process.	I.2.2
9.2.2.C	C. Requirements of applicable codes and standards, including acceptance criteria for the special process.	I.2.3
9.2.3 9.2.3.A	9.2.3 Qualification of Nondestructive Examination Personnel A.Nondestructive examination shall include radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, and leak testing.	I.3 I.3.1
9.2.3.B	B.Personnel that perform nondestructive examinations shall be qualified in accordance with the American Society for Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition. In lieu of the three year recertification interval specified in SNT-TC-1A, June 1980 edition, Level III Nondestructive examination personnel may be recertified on a five year interval.	I.3.2
9.2.3.C	C. The Affected Organization shall establish implementing documents for the control and administration for the training, examination, and certification of nondestructive examination personnel.	I.3.3
Section 10	INSPECTION	J
10.0 10.2.1	10.2 REQUIREMENTS 10.2.1 Inspection Planning Inspection planning shall be performed, documented and include:	 J.1
10.2.1.A	A.Identification of each work operation where inspection is necessary to ensure quality and implementing documents that will be used to perform the inspections.	J.1.1
10.2.1.B	B. Identification of the characteristics to be inspected andidentification of when, during the work process, inspections are to be performed.	J.1.2
10.2.1.C	C. Identification of inspection or process monitoring methods to be employed.	J.1.3
10.2.1.D	D.The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.	J.1.4
10.2.1.E	E.Identification of the functional qualification level (category or class) of personnel performing inspections.	J.1.5
10.2.1.F	F.Identification of acceptance criteria.	J.1.6
10.2.1.G	G.Identification of sampling requirements.	J.1.7
10.2.1.H	H.Methods to record inspection results.	J.1.8
10.2.1.I	I.Selection and identification of the measuring and test equipment to be used to perform the inspection to ensure that the equipment is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function.	J.1.9
10.2.2 10.2.2.A	10.2.2Selecting Inspection Personnel to Perform Inspections A. The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to the requirements of this Section.	J.2 J.2.1
10.2.2.B	B. Data recorders, equipment operators, or other inspection team members who are supervised by a qualified inspector shall not be required to be a qualified inspector.	J.2.2

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10.2.2.C	C. The inspections shall be performed by personnel other than those who performed or directly supervised the item being inspected and are independent of the organization directly responsible for that item. These personnel shall not report directly to the immediate supervisor responsible for the item being examined.	J.2.3
10.2.3	10.2.3Inspection Hold Points	J.3
10.2.3.A	A.When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization placing the hold point, then the specific hold points shall be indicated in implementing documents.	J.3.1
10.2.3.B	B.Consent to waive specified hold points shall be documented before continuing work beyond the designated hold point.	J.3.2
10.2.4	10.2.4Statistical Sampling When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method shall be based on recognized standard practices	J.4
10.2.5	10.2.5In-Process Inspections and Monitoring	J.5
10.2.5.A	A.Items in-process shall be inspected when necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.	J.5.1
10.2.5.B	B.Inspection and process monitoring both shall be conducted when control is inadequate with only one method.	J.5.2
10.2.5.C	C.A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process.	J.5.3
10.2.5.D	D.Controls shall be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the process.	J.5.4
10.2.6	10.2.6Final Inspection	J.6
10.2.6.A	A.Finished items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.	J.6.1
10.2.6.B	B.Documentation not previously examined shall be examined for adequacy and completeness.	J.6.2
10.2.6.C	C. Final inspections shall include a review of the results and resolution of nonconformances identified by earlier inspections.	J.6.3
10.2.7	10.2.7 Accepting Items	J.7
10.2.7.A	A.The acceptance of an item shall be documented and approved by qualified and authorized personnel.	J.7.1
10.2.7.B	B.The inspection status of an item shall be identified according to Section 14.0.	J.7.2
10.2.8	10.2.8 Inspection Documentation Inspection documentation shall identify:	J.8
10.2.8.A	A. The item inspected.	J.8.1
10.2.8.B	B.The date of inspection.	J.8.2
10.2.8.C	C.The name of the inspector, or the inspector's unique identifier, who documented, evaluated, and determined acceptability.	J.8.3

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10.2.8.D	D.The name of the data recorder, as applicable.	J.8.4
10.2.8.E	E. The type of observation or method of inspection.	J.8.5
10.2.8.F	F. The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance.	J.8.6
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10.2.8.H	H..Measuring and test equipment used during the inspection including the identification number and the most recent calibration date.	J.8.8
10.2.8.I	I.Reference to information on actions taken in connection with nonconformances, as applicable.	J.8.9
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10.2.9.B	B. Determination of Initial Capabilities The capabilities of a candidate for certification shall be initially determined by an evaluation of the candidate's education, experience, and training; and either examination results or capability demonstration. The evaluation shall be performed to the requirements of the applicable functional level, and education and experience requirements of this Section.	J.9.2
10.2.9.C	C. Indoctrination and Training of Inspection and Test Personnel	J.9.3
10.2.9.C.1	1.Inspection and test personnel shall be indoctrinated to the technical objectives and requirements of the applicable codes and standards and the quality assurance program requirements that are to be employed in executing their responsibilities.	J.9.3.1
10.2.9.C.2	2. The need for formal training shall be determined, and training shall be conducted as required to qualify personnel for performing inspections and tests.	J.9.3.2
10.2.9.C.3	3.On-the-job training, with emphasis on hands-on experience gained through actual performance of inspections and test, shall be included in the training program.	J.9.3.3
10.2.9.D	D. Functional Qualification Levels of Inspection and Test Personnel Three levels of functional qualification shall be used depending on the complexity of the functions involved. The criteria for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional work.	J.9.4
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10.2.9.E.2	2.Level II Inspection personnel shall meet the following education and experience requirements:	J.9.5.2

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10.2.9.F	F. Physical Requirements for Inspection and Test Personnel	J.9.6
10.2.9.G	G. Certifying the Qualifications of Inspection and Test Personnel	J.9.7
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10.2.9.I	I. Maintaining Qualification Documentation for Inspection and Test Personnel.	J.9.9
Section 11	TEST CONTROL	K
11.2	Requirements	
11.2.1	Test Planning Test planning shall include:	K.1 K.1.1
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11.2.1B.	B.Identification of item to be tested and the test requirements and acceptance limits, including required levels of precision and accuracy.	K.1.2
11.2.1C.	C.Identification of test methods to be employed and instructions for performing the test.	K.1.3
11.2.1D.	D.Test prerequisites that address calibrated instrumentation, appropriate and adequate test equipment and instrumentation, trained personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions, and provisions for data acquisition.	K.1.4
11.2.1E.	E.Mandatory hold points.	K.1.5
11.2.1F.	F.Methods to record data and results.	K.1.6
11.2.1G.	G.Provisions for ensuring that prerequisites for the given test have been met.	K.1.7
11.2.1H.	H.Selection and identification of the measuring and test equipment to be used to perform the test to ensure that the equipment is of the proper type, range accuracy, and tolerance to accomplish the intended function.	K.1.8
11.2.1I.	I.Identification of the functional qualification level of personnel performing tests.	K.1.9
11.2.2	Performing Tests Tests shall be performed in accordance with implementing documents that address the following requirements as applicable:	K.2
11.2.2A.	A.Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel.	K.2.1
11.2.2B.	B.Include or reference test objectives and provisions for ensuring that prerequisites for the given test have been met, adequate calibrated instrumentation is available and use, necessary monitoring is performed, and suitable environmental conditions are maintained.	K.2.2
11.2.2C.	C.Test requirements and acceptance criteria provided or approved by the organization responsible for the design or the item to be tested unless otherwise designate.	K.2.3
11.2.2D.	D.Test requirements and acceptance criteria based upon specified requirements contained in applicable design or other pertinent technical documents.	K.2.4
11.2.2E.	E.Potential sources of uncertainty and error. Test parameters affected by potential sources of uncertainty and error shall be identified and controlled.	K.2.5

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11.2.3	11.2.3Use of Other Testing Documents	K.3
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11.2.3A.:2s	If used, then they shall incorporate the information directly into the approved test implementing document, or shall be incorporated by reference in the approved test implementing document.	K.3.1.2
11.2.3B.	B.Implementing documents shall include adequate supplemental instructions as required to ensure the required quality of the testing work.	K.3.2
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11.2.4A.	A.Test results shall be documented and their conformance with acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure that test requirements have been satisfied.	K.4.1
11.2.4B.	B.The test status of an item shall be identified in accordance with Section 14.0	K.4.2
11.2.5	11.2.5Test documentation Test documentation shall identify the:	K.5
11.2.5A.	A.Item or work product tested.	K.5.1
11.2.5B.	B.Date of test.	K.5.2
11.2.5C.	C.Name of the tester and data recorders.	K.5.3
11.2.5D.	D.Type of observation and method of testing.	K.5.4
11.2.5E.	E.Identification of test criteria or reference documents used to determine acceptance.	K.5.5
11.2.5F.	F.Results and acceptability of the test.	K.5.6
11.2.5G.	G.Actions taken in connection with any nonconformances noted.	K.5.7
11.2.5H.	H.Name of the person evaluating the test results.	K.5.8
11.2.5I.	I.Identification of the measuring and test equipment used during the test including the identification number and the most recent calibrated date.	K.5.9
11.2.6	Qualification of Test Personnel Personnel who perform testing shall be qualified according to the requirements of Section 10.0.	K.6
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12.0	Requirements	
12.1	12.2.1Calibration	L.1
12.2.1.A	A.Measuring and test equipment including equipment that contains software or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, or prior to use, against reference calibration standards having traceability to nationally recognized standards. Software developed or modified by the user shall be controlled in accordance with Supplement I, Software. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented.	L.1.1
12.2.1.B	B.Calibration standards shall have a greater accuracy than the required accuracy of the measuring and test equipment being calibrated.	L.1.2

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12.2.1.B.1	1.If calibration standards with a greater accuracy than required of the measuring and test equipment being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used if they can be shown to be adequate for the requirements.	L.1.2.1
12.2.1.B.2	2.The basis for the calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified.	L.1.2.2
12.2.1.C	C.The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. For measuring and test equipment used in one-time-only applications, the calibration shall be done both before and after use.	L.1.3
12.2.1.D	D.A calibration or calibration check shall be performed when the accuracy of calibrated measuring and test equipment is suspect.	L.1.4
12.2.1.E	E.Calibrated measuring and test equipment shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration.	L.1.5
12.2.1.F	F.Calibrated measuring and test equipment shall be uniquely identified to provide traceability to its calibration data.	L.1.6
12.2.1.G	G.Updates to software contained in measuring and test equipment that effect calibration, require recalibration of the equipment prior to use.	L.1.7
12.2.2	12.2.2 Documenting the Use of Measuring and Test Equipment The use of measuring and test equipment shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.	L.2
12.2.3 12.2.3.A 12.2.3.A.1	12.2.3Out-of-Calibration Measuring and Test Equipment A.Measuring and test equipment shall be considered to be out-of-calibration and not be used until calibrated if any of the following conditions exist: 1.The calibration due date or interval has passed without recalibration.	L.3 L.3.1.1
12.2.3.A.2	2.The device produces results known to be in error.	L.3.1.2
12.2.3.B	B.Out-of-Calibration measuring and test equipment shall be controlled. The controls shall include the following requirements:	L.3.2
12.2.3.B.1	1.Out-of-Calibration measuring and test equipment shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated.	L.3.2.1
12.2.3.B.2	2.When measuring and test equipment is found out-of-calibration during recalibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.	L.3.2.2
12.2.3.B.2.a	a.The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.	L.3.2.2.1
12.2.3.B.2.b	b.The evaluation shall be documented.	L.3.2.2.2
12.2.3.C	C.If any measuring and test equipment is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced.	L.3.3

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12.2.4	12.2.4 Lost Measuring and Test Equipment When measuring and test equipment is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated. A. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested. B. The evaluation shall be documented.	L.4
12.2.5	12.2.5 Measuring and test equipment shall be properly handled and stored to maintain accuracy.	L.5
12.2.6	12.2.6 Calibration and control shall not be required for rulers, tape measures, levels, and other normal commercial equipment that provides adequate accuracy.	L.6
12.2.7 12.2.7.A	12.2.7 Measuring and Test Equipment Documentation Measuring and test equipment calibration documentation shall include the following information: A.Identification of the measuring or test equipment calibrated.	L.7 L.7.1
12.2.7.B	B.Traceability to the calibration standard used for calibration.	L.7.2
12.2.7.C	C.Calibration data.	L.7.3
12.2.7.D	D.Identification of the individual performing the calibration.	L.7.4
12.2.7.E	E.Identification of the date of calibration and the recalibration due date or interval, as appropriate.	L.7.5
12.2.7.F	F.Results of the calibration and statement of acceptability.	L.7.6
12.2.7.G	G.Reference to any actions taken in connection with out-of-calibration or nonconforming measuring and test equipment including evaluation results, as appropriate.	L.7.7
12.2.7.H	H.Identification of the implementing document (including revision level) used in performing the calibration.	L.7.8
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13.0 13.2.1 13.2.1.A	13.2REQUIREMENTS 13.2.1 Controls A.Handling, storage, cleaning, packaging, shipping, and preservation of items shall be conducted in accordance with established work and inspection implementing documents, shipping instructions, or other specified documents.	 M.1 M.1.1
13.2.1.B	B.If required for critical, sensitive, perishable, or high-value articles, specific implementing documents for handling, storage, cleaning, packaging, shipping, and preservation shall be prepared and used.	M.1.2
13.2.2 13.2.2.A	13.2.2Special Equipment, Tools, and Environments A. If required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas and specific moisture and temperature levels) shall be specified and provided.	M.2 M.2.1
13.2.2.B	B. If special equipment and environments are used, provisions shall be made for their verification.	M.2.2
13.2.2.C	C. Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling.	M.2.3

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13.2.2.D	D.Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with implementing documents to verify that the tools and equipment are adequately maintained.	M.2.4
13.2.2.E	E. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.	M.2.5
13.2.3	13.2.3 Marking and Labeling	M.3
13.2.3.A	A.Measures shall be established for marking and labeling for the packaging, shipping, handling, and storage of items as necessary to adequately identify, maintain, and preserve the item.	M.3.1
13.2.3.B	B. Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.	M.3.2
Section 14	INSPECTION TEST AND OPERATING STATUS	N
14.0	Requirements	
14.2.1	14.2.1Identifying Items	N.1
14.2.1.A	A.Items that have satisfactorily passed required inspections and tests shall be identified.	N.1.1
14.2.1.B	B.The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests.	N.1.2
14.2.2	14.2.2Indicating Status	N.2
14.2.2.A	A. The status of required inspection and tests of items shall be indicated when necessary to preclude inadvertent by-passing of such inspections and tests.	N.2.1
14.2.2.B	B.The status of inspections and tests shall be identified either on the items or in documents traceable to the items.	N.2.2
14.2.2.C	C.Status shall be maintained through the use of legible and easily recognizable status indicators (such as tags, markings, labels, and stamps), or other means (such as travelers, inspection, or test records).	N.2.3
14.2.2.D	D.The authority for applying and removing status indicators shall be specified.	N.2.4
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15.2.1.B	B.Nonconformance documentation shall be reviewed, and recommended dispositions of nonconforming items shall be proposed. The review shall include determining the need for corrective action according to the requirements of Section 16.0, Corrective Action. In addition, organizations affected by the nonconformance shall be notified.	O. 1.2
15.2.1.C	C.Recommended dispositions shall be evaluated and approved.	O.1.3
15.2.1.D	D.Personnel performing evaluations of recommended dispositions shall have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements, and access to pertinent background information.	O.1.4
15.2.1.E	E.The responsibility and authority for reviewing, evaluating approving the disposition, and closing nonconformances shall be specified.	O.1.5

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15.2.1.F	F.Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition.	O.1.6
15.2.2	15.2.2Identifying Nonconforming Items	O.2
15.2.2.A	A. Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect their end use. The identification shall be legible and easily recognizable.	O.2.1
15.2.2.B	B. If the identification of a nonconforming item is not practical, then the container, package, or segregated storage area, as appropriate, shall be identified.	O.2.2
15.2.3	15.2.3Segregating Nonconforming Items	O.3
15.2.3.A	A. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.	O.3.1
15.2.3.B	B. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use.	O.3.2
15.2.4	15.2.4 Disposition of Nonconforming Items	O.4
15.2.4.A	A. The disposition of "use-as-is," "reject," "repair," or "rework" for nonconforming items shall be identified and documented.	O.4.1
15.2.4.B	B. The technical justification for the acceptability of a nonconforming item that has been dispositioned "repair" or "use-as-is" shall be documented.	O.4.2
15.2.4.C	C. Items that do not meet original design requirements that are dispositioned "use-as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design.	O.4.3
15.2.4.C.1	1. If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance.	O.4.3.1
15.2.4.C.2	2. Any document or Quality Assurance record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation; and, when each document or record is changed, the justification for the change shall identify the nonconformance documentation.	O.4.3.2
15.2.4.D	D. The disposition of an item to be reworked, or repaired shall contain a requirement to reexamine (inspect, test, or nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be reexamined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.	O.4.4
15.2.5	15.2.5Quality Trending Nonconformance documentation shall be periodically analyzed by the Quality Assurance organization to identify quality trends in accordance with Section 16.0, Corrective Action.	O.5
Section 16.0,	CORRECTIVE ACTION	P
16.2	16.2REQUIREMENTS	
16.2.1	16.2.1 Identifying Conditions Adverse to Quality A condition adverse to quality shall be identified when the Quality Assurance Requirements Document (QARD) or an implementing document requirement is not met.	P.1

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16.2.2	16.2.2Classification of Conditions Adverse to Quality	P.2
16.2.2A.	A.Conditions adverse to quality shall be classified in regard to their significance, and corrective actions shall be taken accordingly.	P.2.1
16.2.2B.	B.Two categories of classification shall be established:	P.2.2
16.2.2B.1.	1.Conditions adverse to quality.	P.2.2.1
16.2.2B.2.	2.Significant conditions adverse to quality.	P.2.2.2
16.2.3	16.2.3Conditions Adverse to	P.3
16.2.3A.	A.Conditions adverse to quality shall be documented and reported to the appropriate levels of management responsible for the conditions and to the quality assurance (QA) organization for tracking.	P.3.1
16.2.3B.	B.Responsible management shall determine the extent of the adverse condition and complete remedial action as soon as practical.	P.3.2
16.2.3C.	C.The QA organization shall concur with the proposed remedial action to ensure that QA program requirements are satisfied.	P.3.3
16.2.4	16.2.4Significant Conditions Adverse to Quality	P.4
16.2.4A.	A.Criteria for determining a significant condition adverse to quality shall be established.	P.4.1
16.2.4B.	B.Significant conditions adverse to quality shall be documented and reported to management responsible for the condition, their upper management, and to the QA organization for tracking.	P.4.2
16.2.4C.	C.Significant conditions adverse to quality shall be evaluated for a stop work condition by the QA organization to determine if stopping work is warranted.	P.4.3
16.2.4C.1.	1.QA management shall issue stop work orders to responsible management after a stop work condition has been identified.	P.4.3.1
16.2.4C.2.	2.QA management shall take appropriate action to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.	P.4.3.2
16.2.4D.	D.Responsible management shall perform investigative action to determine the extent and impact of the condition, and document the results.	P.4.4
16.2.4E.:s1	E.Responsible management shall determine, document, and complete remedial action.	P.4.5.1
16.2.4E.:s2	Responsible management shall also determine the root cause of the problem and take corrective action to prevent recurrence as soon as practical.	P.4.5.2
16.2.4F.	F.The QA organization shall concur with the proposed corrective action including remedial action, the root cause, and actions taken to prevent recurrence to ensure that QA program requirements are satisfied.	P.4.6
16.2.5	16.2.5 The QA organization shall verify implementation of corrective actions taken for all reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete.	P.5
16.2.6	16.2.6Quality Trending	P.6
16.2.6A.	A.The QA organization shall establish criteria for determining adverse quality trends.	P.6.1
16.2.6B.	B.Reports of nonconformance and conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes.	P.6.2

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16.2.6C.	C.Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends.	P.6.3
16.2.6D.	D.Trend evaluations shall be distributed to Affected Organization management.	P.6.4
16.2.6E.	E.Identified adverse trends shall be reported to the management of the organization responsible for corrective action.	P.6.5
Section 17	QUALITY ASSURANCE RECORDS	Q
17.2	17.2 REQUIREMENTS	
17.2.1	17.2.1 Classifying Quality Assurance Records QA records shall be classified as lifetime or nonpermanent.	Q.1
17.2.1A.	A.Documents that meet the following requirements shall be classified as lifetime QA records:	Q.1.1
17.2.1A.1.	1.Documents that provide evidence of the quality of items on a Q-List.	Q.1.1.1
17.2.1A.2.	2.Documents that provide evidence of the quality of activities related to items on a Q-List.	Q.1.1.2
17.2.1A.3.	3.Documents that provide evidence of the quality of site characterization data and samples.	Q.1.1.3
17.2.1A.4.	4.Documents that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.	Q.1.1.4
17.2.1A.5.	5.Documents that provide evidence of the quality of the production process for the high-level waste form and acceptance of the high-level waste form itself.	Q.1.1.5
17.2.1A.6.	6.Documents that provide evidence of the quality of those activities associated with the characterization of DOE spent fuel, and conditioning through acceptance of DOE spent fuel.	Q.1.1.6
17.2.1A.7.	7.Personnel training and qualification documents for individuals executing QA program requirements.	Q.1.1.7
17.2.1A.8.	8.Documents which are implementing documents as described in Section 5.0, Implementing Documents.	Q.1.1.8
17.2.1B.	B.Documents that do not meet the requirements for lifetime QA records, but provide objective evidence that the QA Program has been properly executed shall be classified as nonpermanent QA records.	Q.1.2
17.2.2	Creating Valid Quality Assurance Records	Q.2
17.2.2A.	A.Implementing documents shall:	Q.2.1
7.2.2A.1.	1.Identify those documents that will become QA records.	Q.2.1.1
17.2.2A.2.	2.Identify the organization responsible for submitting the QA records to the records management system.	Q.2.1.2
17.2.2B.	B.Individuals creating QA records shall ensure that the QA records are legible, accurate, complete appropriate to the work accomplished, and identifiable to the items(s) or activity(s) to which they apply.	Q.2.2
17.2.2C.	C.Individuals handling QA records shall protect them from damage or los.	Q.2.3
17.2.2D.:s1	D.Records shall be considered QA records when stamped, initiated, or signed and dated as complete.	Q.2.4.1
17.2.2D.:s2	If the nature of the record (such as magnetic or optical media) precludes stamping, initialing, or signing, then other means of identifying the record as complete by authorized personnel are permitted.	Q.2.4.2
17.2.2E.	E.QA records may be original or copies.	Q.2.5

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17.2.3	17.2.3 Receiving and Indexing Quality Assurance Records A receipt control system shall be established for QA records according to the following requirements:	Q.3
17.2.3A.	A.An individual or organization shall be assigned the responsibility for receiving QA records.	Q.3.1
17.2.3B.	B.A method for verifying that the QA records are those designated.	Q.3.2
17.2.3C.	C.QA records shall be protected from damage, deterioration, or loss when received.	Q.3.3
17.2.3D.	D.Legibility and completeness of QA records shall be verified.	Q.3.4
17.2.3E.	E.The receipt control system shall permit a current and accurate assessment of the status of QA records during processing.	Q.3.5
17.2.3F.	F.QA records shall be indexed to ensure retrievability.	Q.3.6
17.2.3F.1.	The indexing system shall include: 1.The location of the QA records within the records management system.	Q.3.6.1
17.2.3F.2.	2.Identification of the item or related activity to which the QA records pertain.	Q.3.6.2
17.2.3F.3.	3.The classification of the QA record.	Q.3.6.3
17.2.3G.	G.QA records shall be submitted to storage after processing has been completed.	Q.3.7
17.2.4	17.2.4 Correcting Information in Quality Assurance Records	Q.4
17.2.4A.	A.Corrections to QA records, including documents that will become QA records shall include the initials or signature of the person authorized to make the correction and the date the correction was made.	Q.4.1
17.2.4B.:1s	B.Corrections to QA records shall be approved by the originating organization.	Q.4.2.1
17.2.4B.:2s	If an organization was originally responsible for approving a particular document and is no longer responsible, the new responsible organization shall be identified.	Q.4.2.2
17.2.5	17.2.5 Storing and Preserving Quality Assurance Records	Q.5
17.2.5A.	A.QA records shall be stored and preserved in predetermined storage facilities in accordance with an approved implementing document that provides:	Q.5.1
17.2.5A.1.	1.A description of the storage facility.	Q.5.1.1
17.2.5A.2.	2.A description of the filing system to be used.	Q.5.1.2
17.2.5A.3.	3.A method for verifying that the QA records received are in agreement with the transmittal document.	Q.5.1.3
17.2.5A.4.	4.A description of controls governing QA record access, retrieval, and removal.	Q.5.1.4
17.2.5A.5.	5.A method for filing supplemental information.	Q.5.1.5
17.2.5A.6.	6.A method for disposition of superseded QA records.	Q.5.1.6
17.2.5B	B.Storage methods shall be developed to preclude deterioration of QA records in accordance with the following:	Q.5.2
17.2.5B.1.	1.The storage area shall minimize the risk of damage or destruction by natural disasters, extremes in environmental conditions and infestations of pests or molds.	Q.5.2.1
17.2.5B.2.	2.Approved filing methods shall require QA records to be firmly attached in binders, or placed in folders or envelopes, for storage in steel file cabinets or on shelving in containers appropriate for the QA record medium being stored.	Q.5.2.2

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17.2.5B.3.	3.The storage arrangement shall provide adequate protection of special processed QA records (such as radiographs, photographs, negatives, microfilm, and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of QA record being stored.	Q.5.2.3
17.2.5B.4.	4.The storage area shall be protected from unauthorized entry, larceny, and vandalism.	Q.5.2.4
17.2.6	17.2.6 Retrieval of Quality Assurance Records A.The records management system shall provide for retrieval of QA records with	Q.6
17.2.6A.	planned retrieval times based on record type.	Q.6.1
17.2.6B.:1s	B.Access to storage facilities shall be controlled.	Q.6.2.1
17.2.6B.:2s	A list shall be maintained designating personnel who are permitted access to the QA records.	Q.6.2.2
17.2.7	Retention of Quality Assurance Records	Q.7
17.2.7A.	A.OCRWM or its designee shall retain and preserve lifetime QA records for the operating life of the item or facility.	Q.7.1
17.2.7B.:1s	B.Nonpermanent QA records shall be retained for a minimum of three years or as specified by procurement documents, whichever is longer.	Q.7.2
17.2.7B.:2s	Nonpermanent QA records shall not be disposed of until the following conditions are met:	Q.7.2.1
17.2.7B.1.	1.Regulatory requirements are satisfied.	
17.2.7B.2.	2.Operational status permits.	Q.7.2.2
17.2.7B.3.	3.Purchaser's requirements are satisfied.	Q.7.2.3
17.2.8.	17.2.8 Turnover of Quality Assurance Records	Q.8
17.2.8A.:1s	A.Affected Organizations shall submit, to Office of Civilian Radioactive Waste Management (OCRWM) or the purchaser, those QA records being temporarily stored by them that are subject to records turnover requirements.	Q.8.1.1
17.2.8A.:2s	The timing of the submittal shall be as records packages become complete, or as items are released for shipment, or as prescribed by the purchaser.	Q.8.1.2
17.2.8B.	B.The OCRWM records management organization shall inventory the submittal, acknowledge receipt, and process the QA records.	Q.8.2
17.2.8C.	C.The responsible OCRWM line organization shall identify those QA records in temporary storage to be submitted for long-term storage to the records management system.	Q.8.3
17.2.9	17.2.9	Q.9
	OCRWM's single storage facility for the storage of lifetime QA records shall meet	Q.9.1
17.2.9A.	the following design and construction requirements:	Q.9.1.1
17.2.9A.1.	1.Reinforced concrete, concrete block, masonry, or equal construction.	
17.2.9A.2.	2.Floor and roof with drainage control. If a floor drain is provided, a check valve or equal shall be included.	Q.9.1.2
17.2.9A.3.	3.Doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2-hour fire rating.	Q.9.1.3
17.2.9A.4.	4.Sealant applied over walls as a moisture or condensation barrier.	Q.9.1.4
17.2.9A.5.	5.Surface sealant on floor providing a hard wear surface to minimize concrete dusting.	Q.9.1.5

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17.2.9A.6.	6.Foundation sealant and provisions for drainage.	Q.9.1.6
17.2.9A.7.	7.Forced air circulation with filter system.	Q.9.1.7
17.2.9A.8.	8.Fire protection system.	Q.9.1.8
17.2.9A.9.:1s	9.Only those penetrations that are used exclusively for fire protection, communication, lighting, or temperature and humidity control are allowed.	Q.9.1.9
17.2.9A.9.:2s	All penetrations shall be sealed or dampered to comply with the minimum 2 hours fire protection rating.	Q.9.1.1.10
17.2.9B.	B.If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria.	Q.9.2
17.2.9C.	C.Construction details shall be reviewed for the adequacy of record protection by a person competent in the technical field of fire protection and fire extinguishing.	Q.9.3
17.2.10	17.2.10Dual Storage Facilities	Q.10
17.2.10A.	A.The OCRWM's dual storage facilities for the storage of lifetime QA records shall provide facilities for copies of each record at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.	Q.10.1
17.2.10B.	B.Dual storage facilities are not required to meet the design and construction requirements specific for a long-term single storage facility.	Q.10.2
17.2.11	17.2.11 The OCRWM and Affected Organizations shall provide for temporary storage of QA records during processing, review, or use until turnover to OCRWM for disposition, according to the following requirements:	Q.11
17.2.11A.	A.QA records shall be temporarily stored in a container or facility with a fire rating of 1 hour, or dual storage shall be provided.	Q.11.1
17.2.11B.	B.For single storage, containers or facilities shall bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection, or be certified by a person competent in the technical field of fire protection.	Q.11.2
17.2.11C.	C.The maximum time limit for keeping QA records in temporary storage shall be specified by OCRWM or the purchaser consistent with the nature or scope of work.	Q.11.3
17.2.12	17.2.12 Organizations originating QA records shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged QA records.	Q.12
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18.2	18.2REQUIREMENTS	
18.2.1	18.2.1Scheduling Internal Audits	R.1
18.2.1A.	A.Internal audits shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.	R.1.1
18.2.1B.	B.Internal audits shall be scheduled at a frequency commensurate with the status and importance of the work.	R.1.2
18.2.1C.	C.Internal audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.	R.1.3

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18.2.1D.	D.Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness.	R.1.4
18.2.1E.	E.Internal audits of work to verify QA program compliance shall be performed annually or at least once during the life of the work, whichever is shorter.	R.1.5
18.2.1F.	F.Internal audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.	R.1.6
18.2.2	18.2.2 Scheduling External Audits	R.2
18.2.2A.:1s	A.The need for, and frequency of, external audits shall be determined after a supplier has been selected to perform work for the office of Civilian Radioactive Waste Management (OCRWM).	R.2.1.1
18.2.2A.:2s	The determination shall be based on the complexity and nature of the items or services being procured.	R.2.1.2
18.2.2B.:1s	B.External audits shall not be required for procured items that are relatively simple and standard in design, manufacturing, and testing, or adaptable to standard or automated inspections or tests of the end item to verify quality characteristics after delivery.	R.2.2.1
18.2.2B.:2s	Rationale for not performing audits for these items shall be documented.	R.2.2.2
18.2.2C.	C.External audits for compliance shall be performed triennially as a minimum with the initial audit to occur as early in the life of the activity as practical.	R.2.3
18.2.2D.	D.Pre-award surveys, if applicable, may serve as the first triennial audit provided: 1.The supplier is implementing the same QA program for other contracts that is proposed for the purchaser's contracts, and	R.2.4
18.2.2D.1.		R.2.4.1
18.2.2D.2.	2.The pre-award survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit.	R.2.4.2
18.2.2E.	E.External audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.	R.2.5
18.2.2F.:1s	F.Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits.	R.2.6
18.2.2F.:2s	This evaluation shall be documented and based on: 1.Review of documentation furnished by the supplier (such as certificates of	
18.2.2F.1.	conformance, nonconformance notices, and corrective actions).	R.2.6.1
18.2.2F.2.	2.Results of previous source verifications, audits, management assessments, and receiving inspections including audits from other sources.	R.2.6.2
18.2.2F.3.	3.Operating experience of identical or similar work furnished by the same supplier.	R.2.6.3
18.2.2F.4.	4.A review of procurement documents to determine what additional work the supplier has received since the initial contract.	R.2.6.4
18.2.2G.	G.The need to schedule additional external audits shall also be evaluated when a major change in the contract scope, work methodology, or organization occurs.	R.2.7
18.2.3	18.2.3Audit Schedule The audit schedule shall be developed annually and revised periodically to ensure that coverage is maintained current.	R.3

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18.2.4 18.2.4A.:1s	18.2.4Audit Planning A.The auditing organization shall develop and document an audit plan for each scheduled audit.	R.4 R.4.1.1
18.2.4A.:2s	This plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used.	R.4.1.2
18.2.4A.:3s	Audits shall include technical evaluations of the applicable procedures, instructions, activities and items.	R.4.1.3
18.2.4B.	B.The scope of each audit shall be based on an evaluation of implementing documents, activities, and items to be audited, the results of previous audits and the impact of significant changes in personnel, organization, or the QA program.	R.4.2
18.2.5.:1s	18.2.5Audit Team Independence The auditing organization shall select and assign auditors who are independent of any direct responsibility for performing the work being audited.	R.5.1
18.2.5.:2s	Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.	R.5.2
18.2.6 18.2.6A.:1s	18.2.6Audit Team Selection A.An audit team shall be identified before beginning each audit.	R.6 R.6.1.1
18.2.6A.:2s	The audit team shall include representatives from the QA organization and when appropriate applicable technical organizations.	R.6.1.2
18.2.6B.	B.A lead auditor shall be appointed to supervise the team, organize and direct the audit, coordinate the preparation and issuance of the audit report, and evaluate responses.	R.6.2
18.2.6C.	C.Lead auditors and auditors shall be qualified in accordance with the requirements of this Sec.	R.6.3
18.2.6D.:s1	D.Technical specialists may be used by the auditing organization to assist in assessing the adequacy of technical processes.	R.6.4.1
18.2.6D.:s2	Technical specialists, when used, shall be qualified in accordance with the requirements of this Sec.	R.6.4.2
18.2.6E.	E.In the case of internal audits, personnel having direct responsibility for performing the work being audited shall not be involved in the selection of the audit team.	R.6.5
18.2.6F.	F.The lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.	R.6.6
18.2.7 18.2.7A.	18.2.7Performing Audits A.The audit team leader shall ensure that the audit team is prepared before starting the audit.	R.7 R.7.1
18.2.7B.	B.Audits shall be performed in accordance with written procedures or checklists.	R.7.2
18.2.7C.	C.Elements that have been selected for audit shall be evaluated against specified requirements.	R.7.3
18.2.7D.	D.Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively.	R.7.4

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18.2.7E.:1s	E.Audit results shall be documented by auditing personnel and reported to and reviewed by management having responsibility for the area audited.	R.7.5.1
18.2.7E.:2s	Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.	R.7.5.2
18.2.7F.	F.Identified conditions adverse to quality shall be documented and corrected in accordance with Section 16.0, Corrective Action.	R.7.6
18.2.7G.	G.Nonconforming items identified during an audit shall be controlled by the audited organization in accordance with Section 15.0, Nonconformance.	R.7.7
18.2.8 18.2.8.:1s	18.2.8Reporting Audit Results The audit report shall be prepared and signed by the audit team leader, and issued to management of the audited organization and Affected Organizations.	R.8 R.8.1
18.2.8.:2s 18.2.8A.	The audit report shall include the following information: A.A description of the audit scope.	 R.8.2
18.2.8B.	B.Identification of the auditors.	R.8.3
18.2.8C.	C.Identification of persons contacted during the audit.	R.8.4
18.2.8D.	D.A summary of the documents reviewed, persons interviewed, and the specific results of the reviews and interviews, that is, a summary of the checklist contents.	R.8.5
18.2.8E.	E.Statement of the effectiveness of the QA program elements which were audited.	R.8.6
18.2.8F.	F.A description of each reported condition adverse to quality in sufficient detail to enable corrective action to be taken by the audited organization according to the requirements of Section 16.0, Corrective Action.	R.8.7
18.2.9	18.2.9Responding to Audits Management of the audited organization shall investigate conditions adverse to quality; determine and schedule corrective action, including measures to prevent recurrence; and notify the auditing organization in writing of the actions taken or planned in accordance with Section 16.0, Corrective Action.	R.9
18.2.10	18.2.10 Evaluating Audit Responses The adequacy of corrective actions for conditions adverse to quality shall be evaluated by the auditing organization in accordance with Section 16.0, Corrective Action.	R.10
18.2.11	18.2.11 Follow-up Action Follow-up action shall be taken by the auditing organization to verify that corrective action is accomplished as scheduled in accordance with the requirements of Section 16.0, Corrective Action.	R.11
18.2.12	18.2.12 Technical specialists selected for auditing assignments shall be indoctrinated and trained in accordance with Section 2.0, Quality Assurance Program, and shall have the level of experience or training commensurate with the scope, complexity or special nature of the work being audited.	R.12
18.2.13. 18.2.13.:1s	18.2.13 Auditor Qualifications Auditors shall have appropriate training or orientation to develop their competence for performing audits.	R.13

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18.2.13.:2s	Competence of personnel performing various audit functions shall be developed by one or a combination of the following methods:	
18.2.13A.	A.QA program orientation to provide a working knowledge and understanding of the Quality Assurance Requirements and Description (QARD), and the implementing documents used to perform audits and report audit results.	R.13.1
18.2.13B.	B.Training programs to provide general and specialized training in audit performance.	R.13.2
18.2.13B.1.	1.General training shall include the fundamentals, objectives, and techniques of performing audits.	R.13.2.1
18.2.13B.2.	2.Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out conditions adverse to quality addressed by corrective action requests.	R.13.2.2
18.2.13C.:1s	C.On-the-job training, guidance, and counseling under the direct supervision of a lead auditor.	R.13.3.1
18.2.13C.:2s	Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.	R.13.3.2
18.2.14	18.2.14	R.14
18.2.14A.	A.A lead auditor shall be capable of organizing and directing audits, reporting audit findings, and evaluating planned and taken corrective action.	R.14.1
18.2.14B.	B.A lead auditor shall be certified as meeting the requirements for education and experience, communication skills, training, audit participation, and passing the examination as provided in this Sec.	R.14.2
18.2.15	18.2.15 Lead Auditor Education and Experience The prospective lead auditor shall have verifiable evidence that a minimum of ten credits have been accumulated under the following scoring system:	R.15
18.2.15A.	A.Education (four credits maximum)	R.15.1
18.2.15A.1.:1s	1.An associate degree from an accredited institution: score one credit.	R.15.1.1
18.2.15A.1.:2s	If the degree is in engineering, physical sciences, mathematics, or QA: score two credits; or	R.15.1.2
18.2.15A.2.:1s	2.A bachelors degree from an accredited institution: score two credits or, if the degree is in engineering, physical sciences, mathematics, or QA: score three credits.	R.15.1.3
18.2.15A.2.:2s	In addition, score one credit for a master's degree in engineering, physical sciences, business management, or QA from an accredited institution.	R.15.1.4
18.2.15B.	B.Experience (nine credits maximum) Technical experience in such areas as scientific investigation, site characterization, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility: score one credit for each full year with a maximum of five credits for this aspect of experience.	R.15.2
18.2.15B.1.	1.If two years of this experience have been in the nuclear-related field: score one additional credit; or	R.15.2.1
18.2.15B.2.	2.If two years of this experience have been in QA: score two additional credits; or	R.15.2.2
18.2.15B.3.	3.If two years of this experience have been in auditing: score three additional credits; or	R.15.2.3
18.2.15B.4.	4.If two years of this experience have been in nuclear-related QA: score three additional credits; or	R.15.2.4
18.2.15B.5.	5.If two years of this experience have been in nuclear-related QA auditing: score four additional credits.	R.15.2.5
18.2.15C.	C.Professional Competence (two credits maximum) For certification of competency in engineering science or QA specialties issued and approved by a state agency or national professional or technical society: score two credits.	R.15.3
18.2.15D.	D.Rights of Management (two credits maximum) When determined appropriate, the auditing organization may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses).	R.15.4
18.2.16.:1s	18.2.16 The prospective lead auditor shall have the capability to communicate effectively, both in writing and orally.	R.16 R.16.1
18.2.16.:2s	These skills shall be attested to in writing by the candidate's supervisor.	R.16.2
18.2.17	18.2.17 Lead Auditor Training	R.17
18.2.17A.	A.Prospective lead auditors shall be trained to the extent necessary to ensure their competence in auditing skills as established by the organization responsible for performing audits.	R.17.1
18.2.17B.	B.Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective lead auditor.	R.17.2
18.2.17B.1.	1.Knowledge and understanding of the QARD and other program-related procedures, codes, standards, regulations, and regulatory guides.	R.17.2.1
18.2.17B.2.	2.General structure of QA programs as a whole and the specific elements of the QARD.	R.17.2.2
18.2.17B.3.:s1	3.Auditing techniques of examining, questioning, evaluating, and reporting.	R.17.2.3.1
18.2.17B.3.:s2	Methods of identifying, following up on, and closing corrective action items.	R.17.2.3.2
18.2.17B.4.	4.Audit planning in functional areas (such as scientific investigation, design, purchasing, construction, fabrication, handling, shipping, storage, cleaning, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification, and safety) of nuclear facilities.	R.17.2.4
18.2.17B.5.	5.On-the-job training to include applicable elements of the audit program.	R.17.2.5
18.2.18	18.2.18 Lead Auditor Audit Participation	R.18
18.2.18.:s1	The prospective lead auditor shall have participated in a minimum of five QA audits within a period of time not to exceed three years prior to the date of certification.	R.18.1
18.2.18.:s2	One audit shall be a nuclear-related QA audit within the year prior to certification.	R.18.2

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18.2.19 18.2.19A.:s1	18.2.19 Lead Auditor Examination A.The prospective lead auditor shall pass an examination that evaluates the comprehension of and ability to apply the audit knowledge described in this Sec.	R.19 R.19.1.1
18.2.19A.:s2	The test shall be oral, written, practical, or any combination.	R.19.1.2
18.2.19B.:s1	B.The development and administration of the examination for a lead auditor is the responsibility of the auditing organization.	R.19.2
   18.2.19B.1.	The auditing organization shall: 1.Maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations.	 R.19.2.1
18.2.19B.2.	2.Develop and maintain objective evidence regarding the type and content of the examination.	R.19.2.2
18.2.20 18.2.20.:s1	18.2.20 Certification of Lead Auditor Qualifications Each lead auditor shall be certified by the auditing organization as being qualified to lead audits.	R.20
  18.2.20A.	This certification shall document the: A.Name of the auditing organization.	 R.20.1
18.2.20B.	B.Name of the lead auditor.	R.20.2
18.2.20C.	C.Date of certification or recertification.	R.20.3
18.2.20D.	D.Basis of certification (such as education, experience, communication skills, and training).	R.20.4
18.2.20E.	E.Signature of the designated representative of the auditing organization responsible for certification.	R.20.5
18.2.21 18.2.21A. 18.2.21A.1.	18.2.21 Maintaining Lead Auditor Proficiency Lead auditors shall maintain their proficiency through one or combination of the following: 1.Regular and active participation in the audit process.	R.21 R.21.1 R.21.1.1
18.2.21A.2.	2.Review and study of codes, standards, implementing documents, instructions, and other documents related to the QA program and program auditing.	R.21.1.2
18.2.21A3.	3.Participation in QA training programs.	R.21.1.3
18.2.21B.:1s	B.Management of the auditing organization shall evaluate the proficiency of lead auditors annually.	R.21.2.1
18.2.21B.:2s	Based on the evaluation, management may choose to extend the qualification, require retraining, or require requalification.	R.21.2.2
18.2.21B.:s3	Management evaluations shall be documented.	R.21.2.3
18.2.21C.:1s	C.Lead auditors who fail to maintain their proficiency for a period of two years or more shall require requalification.	R.21.3.1
18.2.21C.:2s	Requalification shall include retraining and re-examination in accordance with this section, and participation as an auditor in at least one nuclear QA audit.	R.21.3.2
SUPPLEMENT I	SOFTWARE	S

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	I.2Requirements I.2.1. A.for developed or modified software, each Affected Organization shall document and approve a specific software life cycle for each software item prior to development of modification of software.	 S.1 S.1.1
I.2.1A.1.:1s	1.Software life cycles shall be defined by control points at which software baseline elements shall be documented.	S.1.1.1
I.2.1A.1.:2s	Software life cycle activities may be performed in an iterative or sequential manner.	S.1.1.2
I.2.1A.2.:1s	2.When the software life cycle is defined for software development or modification within an Affected Organization, the documentation requirements of Subsections I.2.3, Software Verification, B and C, I.2.4, Software Validation, F and G, and I.2.5, Documentation, A, B, and C shall be established.	S.1.1.3
I.2.1A.2.:2s	All other requirements apply subsequent to establishment of the software life cycle.	S.1.1.4
I.2.1A.3.	3.Reviews of software baselines shall be performed and documented at the software control points.	S.1.1.5
I.2.1B. I.2.1B.1.	For acquired software the following requirements shall be met: 1.Perform installation tests to ensure that software performs as required in the operational environment.	S.1.2 S.1.2.1
I.2.1B.2.:s1	2.Perform validation in accordance with Subsection I.2.4, Software Validation, D, E, F, and G using test cases developed independently of the software developer.	S.1.2.2
I.2.1B.2.:s2	Additional test cases provided by the developer may be used to supplement this process with justification for their use.	S.1.2.3
I.2.1B.3.	3.Document in accordance with the requirements of Subsection I.2.5, documentation, A, B, C.2, and C.6 as applicable.	S.1.2.4
I.2.1B.4.	4.Perform and document reviews of software baselines.	S.1.2.5
I.2.1B.5.	5.Place under the configuration controls in accordance with Subsection I.2l6, Software configuration Management.	S.1.2.6
I.2.1B.6.	6.Implement a defect reporting and resolution system in accordance with Subsection I.2.7, Defect Reporting and Resolution.	S.1.2.7
I.2.1B.7.	7.Control the use of software in accordance with subsection I.2.8, Control of the Use of Software.	S.1.2.8
I.2.1C. I.2.1C.1.	Software, including macros, that can be verified by visual inspection and/or hand calculations shall have limited requirements applied as follows: 1.Listing of the version and any subsequent changes to the software.	S.1.3 S.1.3.1
I.2.1C.2.	2.Documentation that the software provides correct results for a specified range o input parameters.	S.1.3.2
I.2.2 I.2.2A.:s1	I.2.2.Software Verification and Software Validation A.Software verification and software validation shall be performed prior to release	S.2 S.2.1.1

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I.2.2A.:s2	In those cases where this requirement cannot be met prior to the release of the software, the portions of software that have not been verified and validated shall be identified and controlled, and written justification of the reason documented.	S.2.1.2
I.2.2B.:s1	B.Software verification and software validation activities shall be performed or reviewed by independent individuals or organizations who did not work on the original software development of modification.	S.2.2.1
I.2.2B.:s2	The person who directed the work may perform these activities with a higher level of management approval and documented justification.	S.2.2.2
I.2.3. I.2.3A.	I.2.3Software Verification A.The software verification shall be performed and documented to ensure that baseline elements meet the established requirements.	S.3 S.3.1
I.2.3B.	B.The verification documentation shall include a description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software verification.	S.3.2
I.2.3C.	C.a record of the results of the execution of planned software verification shall be generated including the extent top which the results agree with the specified acceptance criteria.	S.3.3
I.2.4 I.2.4A.	I.2.4Software Validation A.Software validation activities (such as the development of test plans and test cases) shall be integrated into the software life cycle.	S.4 S.4.1
I.2.4B.	B.Testing shall be the primary methods of software validation.	S.4.2
I.2.4C.	C.Software validation of modifications to released software items shall include regression testing.	S.4.3
I.2.4D.	D.Software validation shall be performed to an approved plan or process.	S.4.4
I.2.4E.	E.The test methods and test cases shall be documented to ensure that software meets the Affected Organization's requirements for its intended use.	S.4.5
I.2.4F.	F.The validation documentation shall include a description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software validation.	S.4.6
I.2.4G.	G.A record of the results of the execution of planned software validation shall be generated including the extent to which the results agree with the specified acceptance criteria.	S.4.7
I.2.5	I.2.5.Documentation Software activities shall be documented sufficiently to demonstrate the ability of the software to meet the needs of the Affected Organization and shall include the following:	S.5
  I.2.5A. I.2.5A.1.	Functional Requirements Information: 1.A description of the overall nature and purpose of the software.	 S.5.1 S.5.1.1
I.2.5A.2.	2.Requirements for its intended use.	S.5.1.2

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I.2.5B. I.2.5B.1. I.2.5B.1.a.	User Information: A description of how to use the software item including: a.Input and output options.	S.5.2 S.5.2.1 S.5.2.1.1
I.2.5B.1.b.	b.Data files, input and output data, defaults, and file formats.	S.5.2.1.2
I.2.5B.1.c.	c.A description of the allowable and tolerable ranges for inputs and outputs.	S.5.2.1.3
I.2.5B.1.d.	d.Anticipated errors and how the user can respond.	S.5.2.1.4
I.2.5B.1.e.	e.The hardware and software environments.	S.5.2.1.5
I.2.5B.2.	2.Available sample problems.	S.5.2.2
I.2.5B.3.	3.Installation procedures.	S.5.2.3
I.2.5C. I.2.5C.1.	Requirements and Design Information: 1.Performance requirements and design constraints.	S.5.3 S.5.3.1
I.2.5C.2.	2.Interfaces with external data, hardware, or other software.	S.5.3.2
I.2.5C.3.	3.Applicable software and hardware operation issues including programming languages and versions, portability, maintainability, reliability, and efficiency.	S.5.3.3
I.2.5C.4.	4.A description of each software item as it relates to the functional requirements.	S.5.3.4
I.2.5C.5.	5.A description of the software structure including software internal interfaces, control logic, and data structure and flow.	S.5.3.5
I.2.5C.6.	6.A description of models and numerical methods.	S.5.3.6
I.2.5C.7.	7.Source code for developed software or software modification.	S.5.3.7
I.2.6. I.2.6.:s1	I.2.6.Software Configuration Management A software configuration management system shall be established to include configuration identification and configuration control and status accounting.	S.6 S.6.1.1
I.2.6.:s2	Software shall be placed under configuration management control as each baseline element is approved.	S.6.1.2
I.2.6A. I.2.6A.1.	Configuration identification shall include: 1.A definition of the baseline elements of each software baseline.	S.6.2 S.6.2.1
I.2.6A.2.	2.A unique identification of each software item to be placed under software configuration management.	S.6.2.2
I.2.6A.2.a.	a.Each version or revision of a software item shall be uniquely identified and labeled.	S.6.2.2.1
I.2.6A.2.b.	b.The software version or revision identifier shall be included with the generated output, when feasible.	S.6.2.2.2
I.2.6A.3.:s1	3.Assignment of unique identifiers that relate baseline documents to their associated software items.	S.6.2.3.1
I.2.6A.3.:s2	Cross-references between baseline documents and associated software shall be maintained.	S.6.2.3.2
I.2.6B. I.2.6B.1.	Configuration control shall include: 1.A release and control process for baseline elements.	S.6.3 S.6.3.1
I.2.6B.2.:s1	2.Changes to baseline elements, including retirement and withdrawal, shall be formally controlled and documented.	S.6.3.2

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I.2.6B.2.:s2	This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baseline elements.	S.6.3.3
I.2.6B.2.a.	a.The change shall be formally evaluated and approved by the organization responsible for approving the baseline element.	S.6.3.3.1
I.2.6B.2.b.	b.Only approved changes shall be made to software baselines.	S.6.3.3.2
I.2.6B.2.c.	c.Information concerning approved changes shall be transmitted to all organizations affected by the changes.	S.6.3.3.3
I.2.6B.2.d.	d.Software verifications shall be performed for the changes as necessary to ensure the changes are appropriately reflected in software documentation and to ensure that document traceability is maintained.	S.6.3.3.4
I.2.6B.2.e.	e.Software validation shall be performed as necessary for the change.	S.6.3.3.5
I.2.6C. I.2.6C.1.	Configuration status accounting shall include: 1.A listing of the approved baseline elements and unique identifiers.	S.6.4 S.6.4.1
I.2.6C.2.	2.The status of proposed and approved changes to the baseline elements.	S.6.4.2
I.2.6C.3.	3.A brief chronology of the software items, including descriptions of the changes made between versions of software items.	S.6.4.3
I.2.7.	I.2.7.Defect Reporting and Resolution A software defect reporting and resolution system shall be implemented.	S.7
I.2.7A.	A.The defect reporting and resolution system shall be integrated with the software configuration management system to ensure formal processing of defect resolutions.	S.7.1
I.2.7B. I.2.7B.1.	Software defect reporting and resolution systems shall include the following controls: 1.Defects shall be documented and resolved.	S.7.2 S.7.2.1
I.2.7B.2.	2.Defects shall be assessed for their impact on previous applications.	S.7.2.2
I.2.7B.3.	3.Resolutions shall be reviewed and approved before changes are made to baseline elements.	S.7.2.3
I.2.7B.4.	4.Notification of identified user organizations.	S.7.2.4
I.2.7C.	C.If a defect is identified in software that adversely impacts previous applications, then the condition adverse to quality shall be documented and controlled in accordance with Section 16.0, Corrective Action.	S.7.3
I.2.8 I.2.8A.	I.2.8Control of the Use of Software A.Affected Organizations shall control and document the use of released software items such that comparable results can be obtained, with any differences explained, through independent replication of the process.	S.8 S.8.1
I.2.8B.	B.Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.	S.8.2
I.2.8C.	C.If use of a software item falls outside the range of validation, further validation shall be performed prior to use.	S.8.3
SUPPLEMENT II	SAMPLE CONTROL	T

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II.0	Requirements	
	II.2.1General Requirements	T.1
II.2.1.A	A.Samples shall be controlled and identified in a manner consistent with their intended use.	T.1.1
II.2.1.B	B.These controls shall identify responsibilities including interfaces between organizations for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use.	T.1.2
II.2.1.C	C.Controls shall include specifics on orientation relative to the location that was sampled, as appropriate.	T.1.3
II.2.2	II.2.2Traceability	T.2
II.2.2.A	A.Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents.	T.2.1
II.2.2.B	B.Sample traceability shall ensure that the sample can be traced at all times from its collection through final use.	T.2.2
II.2.3	II.2.3Identification	T.3
II.2.3.A	A.Identification shall be maintained on the samples or in a manner which ensures that identification is established and maintained.	T.3.1
II.2.3.B	B.Samples shall be identified from their initial collection through final use.	T.3.2
II.2.3.C	C.Sample identification is documented and checked before released for use.	T.3.3
II.2.3.D	D.Sample identification methods shall include use of physical markings.	T.3.4
II.2.3.E	E. If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural control).	T.3.5
II.2.3.F II.2.3.F.1	F. Physical markings, when used, shall: 1.Be applied using materials and methods that provide a clear and legible identification.	 T.3.6.1
II.2.3.F.2	2.Not detrimentally affect the sample content or form.	T.3.6.2
II.2.3.F.3	3.Be transferred to each identified sample part when the sample is subdivided.	T.3.6.3
II.2.3.F.4	4.Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted.	T.3.6.4
II.2.4	II.2.4Conditional Requirements The controls for samples shall address the following requirements, as applicable:	T.4
II.2.4.A	A.If documents (such as the Site Characterization Plan, test plans, study plans, or job packages) contain specific identification or traceability requirements (such as identification or traceability of the sample to applicable study plan, site characterization activity, or other records), those specified controls shall be implemented.	T.4.1
II.2.4.B	B.If samples have limited use or storage life, then methods shall be established that preclude using the sample beyond its intended use or storage life.	T.4.2
II.2.4.C	C.If sample storage is required, then methods shall be established for the control of sample identification that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:	T.4.3

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II.2.4.C.1	1.Maintenance or replacement of markings and identification tags damaged during handling or aging.	T.4.3.1
II.2.4.C.2	2.Protection of identification markings subject to excessive deterioration resulting from environmental exposure.	T.4.3.2
II.2.4.C.3	3.Updating related documentation.	T.4.3.3
II.2.5	II.2.5Archiving Samples Implementing documents shall specify the representative samples to be archived if the need to archive samples is identified.	T.5
II.2.6 II.2.6.A	II.2.6Handling, Storage, and Shipping A.Handling, storage, cleaning, packaging, shipping, and preservation of samples shall be conducted in accordance with established implementing documents or other specified documents.	T.6 T.6.1
II.2.6.B	B.If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, shipping, and preservation shall be identified and used.	T.6.2
II.2.6.C	C. Measures shall be established for the marking and labeling for packaging, shipping, handling, and storage of samples as necessary to adequately identify, maintain, and preserve the sample.	T.6.3
II.2.6.D	D.Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.	T.6.4
II.2.6.E	E.If required for particular samples, special equipment (such as containers) and special protective environments (such as inert gas, and moisture and temperature limits) shall be specified and provided.	T.6.5
II.2.6.F	F.Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling.	T.6.6
II.2.6.F.1	1.Special handling tools and equipment shall be inspected and tested in accordance with implementing documents and at specified time intervals to verify that the tools and equipment are adequately maintained.	T.6.6.1
II.2.6.F.2	2.Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.	T.6.6.2
II.2.7 II.2.7.A	II.2.7Disposition of Nonconforming Samples A.Samples that do not meet requirements specified in work controlling documents (such as Job Packages, Travelers, or Work Requests) shall be documented, evaluated, identified, and segregated in accordance with Section 15.0, Nonconformances.	T.7 T.7.1
II.2.7.B	B. The disposition for nonconforming samples shall be identified and documented and shall be limited to “use-as-is,” “limited use,” or “discard.”	T.7.2
SUPPLEMENT III	SCIENTIFIC INVESTIGATIONS	U
III.2 III.2.1 III.2.1A.	III.2Requirements III.2.1Planning Scientific Investigations A.Scientific investigations shall be planned in accordance with Section 2.0, Quality Assurance Program.	 U.1 U.1.1
III.2.1B.	B.Planning shall be coordinated with organizations providing input to or using the results of the investigation.	U.1.2

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III.2.1C.	C.Planning shall address provisions for determining the accuracy, precision, and representativeness of results.	U.1.3
III.2.2 III.2.2A.	III.2.2Performing Scientific Investigations A.Scientific investigations shall be performed using scientific notebooks, implementing documents, or a combination of both.	U.2 U.2.1
III.2.2B. III.2.2B.1.	B.Scientific notebooks shall contain the following: 1.Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics.	U.2.2 U.2.2.1
III.2.2B.2.	2.Identification of methods(s) and computer programs to be used.	U.2.2.2
III.2.2B.3.	3.Identification of any samples or measuring and test equipment used.	U.2.2.3
III.2.2B.4.	4.Description of the work as it was performed and results obtained names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries.	U.2.2.4
III.2.2B.5.	5.Description of changes made to methods used, as appropriate.	U.2.2.5
III.2.2C.1.	Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to: 1.Retrace the investigations and confirm the results, or	U.2.3 U.2.3.1
III.2.2C.2.	2.Repeat the investigation and achieve comparable results, without recourse to the original investigator.	U.2.3.2
III.2.3 III.2.3A.	III.2.3Data Identification A.Data shall be identified in a manner that facilitates traceability to associated documentation.	U.3 U.3.1
III.2.3B.	B.Data shall be identified in a manner that facilitates traceability to its qualification status.	U.3.2
III.2.3C.	C.Identification and traceability shall be maintained throughout the lifetime of the data.	U.3.3
III.2.4 III.2.4A.	III.2.4Data Review, Adequacy, and Usage A.Data reduction shall be described to permit independent reproducibility by another qualified individual.	U.4 U.4.1
III.2.4B.	B.Data that are directly relied upon to address safety and waste isolation issues shall be qualified from origin, accepted, or undergo a qualification process.	U.4.2
III.2.4B.1.	1.Data qualified from origin shall be reviewed by individuals other than those who acquired or developed the data in accordance with established review criteria to ensure technical correctness.	U.4.2.1
III.2.4B.2	2.Accepted data need not undergo the qualification process. The rationale for considering data to be accepted shall be documented.	U.4.2.2
III.2.4B.3.:1s	3.Existing data may be used in scientific investigation and design activities, provided traceability to its status as existing data is maintained.	U.4.2.3
III.2.4B.3.:2s	Existing data directly relied upon to address safety and waste isolation issues shall be qualified in accordance with III.2.4 at appropriate times during the scientific investigations and design process and before:	U.4.2.4
III.2.4B.3.a.	a.OCRWM acceptance of DOE-owned high-level waste or spent nuclear fuel;	U.4.2.4.1
III.2.4B.3.b.	b.Submittal of the License Application;	U.4.2.4.2

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III.2.4B.3.c.	c.Relying on the item for which the data were used as design input, to perform its function; or	U.4.2.4.3
III.2.4B.3.d.	d.Data are relied upon to resolve safety or waste isolation issues.	U.4.2.4.4
III.2.4C.	Existing data directly relied upon to address safety and waste isolation issues shall be qualified by one or a combination of the methods that follow: 1.Determination that the controls under which the data were generated are similar in scope, requirements, and implementation to the QARD.	U.4.3
III.2.4C.1.		U.4.3.1
III.2.4C.2.	2.Evaluation of corroborating data - Rationale for selecting one set of data to corroborate another set of data shall be clearly explained and justified.	U.4.3.2
III.2.4C.3.	3.Confirmatory testing.	U.4.3.3
III.2.4C.4.	4.Peer review in accordance with Section 2.0, Quality Assurance Program.	U.4.3.4
III.2.4C.5.:1s	Technical Assessment to independently evaluate data which includes one or a combination of the following:	U.4.3.5
III.2.4C.5.a.	a.Determination that the employed methodology is acceptable;	U.4.3.5.1
III.2.4C.5.b.	b.Determination that confidence in the data acquisition or developmental results is warranted; or	U.4.3.5.2
III.2.4C.5.c.	c.Confirmation that the data have been used in similar applications.	U.4.3.5.3
III.2.4C.5.:2s	Methods 1,2, and 3 above shall include a review to determine the technical correctness of the data in accordance with established review criteria.	U.4.3.6.1
III.2.4C.5.:3s	The qualification process shall be planned and documented.	U.4.3.6.2
III.2.4C.5.:4s	Documentation shall include the acceptance criteria used to determine if the data are qualified, and rationale for discontinuing any qualification methods abandoned after the initiation of the qualification process.	U.4.3.6.3
III.2.5	III.2.5 Technical Report Review chnical reports shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review.	U.5

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III.2.6	III.2.6Model Development and Use A.The development of models of natural phenomena shall be documented.	U.6
III.2.6A.:1s		U.6.1.1
III.2.6A.:2s	Documentation shall identify principal lines of investigation considered.	U.6.1.2
III.2.6B.	B.Models of natural phenomena shall be validated to the extent practical to confirm that the mathematical representation appropriately depicts the natural phenomena.	U.6.2
III.2.6C.	C.Model validation shall be accomplished by comparing analysis results against data acquired from laboratory, field experiments, natural analogue studies, or observations that were not used in the original development of the model.	U.6.3
III.2.6C.1.	1.When data are not available from these sources, alternative approaches shall be documented and used for model validation.	U.6.3.1
III.2.6C.2.	2.the need to perform a peer review as an alternative approach shall be consistent with consideration criteria specified for peer review in Section 2.0, Quality Assurance Program.	U.6.3.2
III.2.6D.	D.The selection and use of models of natural phenomena shall be documented and justified.	U.6.4
SUPPLEMENT V	CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA	V
V.2	V.2Requirements	
V.2.1	V.2.1Control of the Electronic Management of Data	V.1
V.2.1A.	The Affected Organization shall establish controls to ensure: A.The completeness and accuracy of the data input.	V.1.1
V.2.1B.	B.The completeness and accuracy of subsequent changes to data input.	V.1.2
V.2.1C.	C.The security of the data is maintained including integrity of the data.	V.1.3
V.2.1D.	D.When data is retrieved using a query language, the query shall be checked to ensure it satisfies the Affected Organization's requirements for its intended use.	V.1.4

Attachment E

Cause Codes

Attachment E

Cause Codes

CauseCode	CodeDesc
01	PROCEDURES/IMPLEMENTING DOCUMENTS
01 A	Procedure not used
01 A a	No/incomplete documents/procedure
01 A b	Lost/missing documents/procedure
01 A c	Procedure difficult to use
01 A d	Procedure not available or inconvenient to use
01 A e	Procedure use not required but should be
01 B	Inadequate/wrong procedure
01 B a	Typographical error
01 B b	Sequence wrong
01 B c	Technical facts/data wrong
01 B d	Requirements:
01 B d (1)	updates not incorporated
01 B d (2)	not covered/addressed
01 B e	Wrong documents/procedure used
01 B f	Wrong revision used
01 B g	Implementing documents/process:
01 B g (1)	not adequate/can't be followed
01 B g (2)	incomplete
01 B g (3)	does not exist
01 B g (4)	Does not describe HOW the requirement will be implemented
01 B h	Conflicting instructions
01 C	Error in following the procedure
01 C a	Format confusing
01 C b	More than one action per step
01 C c	Multiple references
01 C d	No signoff space
01 C e	Checklist misused
01 C f	Information/Data/Computation wrong or incomplete
01 C g	Ambiguous instructions
01 C h	Inadequate limits/parameters
01 D	Self imposed requirement - not needed for QARD compliance
02	PERSONNEL - HUMAN PERFORMANCE
02 A	Lack of attention to a task
02 A a	Carelessness
02 A b	Oversight
02 A c	Work overload
02 A d	Procedure not used, or used improperly
02 A e	Wrong revision used
02 A f	Lack of direction
02 B	Lack of Qualification
03	MANAGEMENT SYSTEM
03 A	Standards, Policies, Administrative Controls (SPAC)
03 A a	No SPAC
03 A b	SPAC not used
03 A c	Inadequate communication of SPAC
03 A d	SPAC Recently changed
03 A e	Inadequate drawings/prints
03 A f	Inadequate accountability
03 B	Immediate supervision
03 B a	Inadequate job/task analysis
03 B b	No preparation/planning
03 B c	Inadequate selection of performer(s)
03 B c (1)	Individual not qualified
03 B c (2)	Team selection not balanced/adequate
03 B d	Performers not trained
03 B e	No supervision during work
03 B f	Infrequent task
03 C	Communications
03 D	No/late communication
03 E	Misunderstood verbal communication
03 F	Audits/Evaluations
03 F a	No Audits/Evaluations
03 F b	Audit checklist misused
04	TRAINING
04 A	No training
04 A a	Decided not to train
04 A b	No learning objective
04 B	Lack of understanding
04 B a	Learning objectives need improvement
04 B b	Lesson plan need improvement
04 B c	Training instructions need improvement
04 B d	Testing need improvement
04 B e	Continued/Refresher training need improvement
04 C	Inadequate training methods
04 C a	Incomplete training
04 C b	Inadequate facilities
04 C c	Continuous training inadequate
04 C d	Inadequate testing or measure of aptitude
05	DESIGN/SCIENTIFIC INVESTIGATION
05 A	Design Documents/ Scientific Investigation
05 A a	Documents do not exist
05 A b	Data/computation wrong, incomplete, or less than adequate
05 A c	Requirements:
05 A c (1)	not identified
05 A c (2)	incorrectly identified
05 A d	Scientific investigation not performed per study plan
05 A e	Problems not anticipated in design or investigation
05 A f	Equipment environment not considered
05 B	Technical Review
05 B a	Review not performed
05 B b	Review inadequate
05 B c	Reviewer lack of independence
06	FABRICATION/INSTALLATION
06 A	Fabrication/installation
06 A a	Fabrication/installation error
06 A b	Fabrication/installation not per design
06 A c	Wrong sequence fabrication/installation
06 A d	Wrong material
06 A e	Defective material
06 A f	Lack of proper tools used for fabrication/installation
06 B	Quality Control
06 B a	No inspection
06 B b	Wrong inspection instructions
06 B c	Wrong inspection technique
07	RELIABILITY SYSTEM
07 A	Inadequate Preventative Maintenance
07 A a	No preventative maintenance for equipment
07 A b	Inadequate preventative maintenance for equipment
07 B	Unreliable Equipment
07 B a	Equipment past design lifetime
07 B b	Equipment repeated failure, previous corrective action inadequate
08	SOFTWARE
08 A	Computer software controls
08 A a	Inadequate software design
08 A b	Inadequate validation, verification or testing

08 A c	Defects:
08 A c (1)	Inadequate defect report
08 A c (2)	Inadequate defect resolution
08 A d	Inadequate software maintenance
08 A e	Inadequate software identification
08 B	Inadequate user information manuals
08 C	Inadequate control of usage
08 D	Inadequate data update
09	PROCUREMENT
09 A	Vendor not in the Approved Supplier List
09 B	Vendor not qualified
09 C	Receiving inspection
09 C a	No receiving inspection
09 C b	Inadequate Receiving inspection
10	MISCELLANEOUS OR MULTIPLE AREAS
10 A	Multiple Causes Present
10 B	Material/Equipment Inadequate
10 C	Unknown
10 D	Natural Causes
10 E	Planned Failure